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DELTA REPORT

10-K

KRRO - FREQUENCY THERAPEUTICS, I
10-K - DECEMBER 31, 2023 COMPARED TO 10-K - DECEMBER 31, 2022

The following comparison report has been automatically generated

TOTAL DELTAS	11179
CHANGES	56
DELETIONS	4826
ADDITIONS	6297

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2022 2023

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR

THE TRANSITION PERIOD FROM TO

Commission File Number file number 001-39062

FREQUENCY THERAPEUTICS, INC. Korro Bio, Inc.

(Exact Name name of Registrant registrant as Specified specified in its Charter)charter)

Delaware

(State or Other Jurisdiction other jurisdiction of

Incorporation incorporation or Organization) organization)

One Kendall Square

75 Hayden Avenue Building 600-700, Suite 300 6-401

Lexington Cambridge, MA

(Address of Principal Executive Offices) principal executive offices)

47-2324450

(I.R.S. Employer

Identification No.)

02421 02139

(Zip Code)

Registrant's telephone number, including area code: (781 617)315-4600 468-1999

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 stock, par value \$0.001 per share	FREQ KRRO	The Nasdaq Global Select Capital Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ Yes No ☒ No ☐

Indicate by check mark if the Registrant registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the Registrant registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

☐

Accelerated filer

☐

Non-accelerated filer

☒

Smaller reporting company

☒

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common stock equity held by non-affiliates of the registrant, based on the closing price of the registrant's shares of common stock as reported on the The Nasdaq Global Select Capital Market on June 30, 2022 June 30, 2023, was \$46.8 12,148,224 million.

The number of shares of Registrant's registrant's Common Stock outstanding as of February 28, 2023 March 21, 2024 was 35,286,837 8,021,946.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the registrant's 2023 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

Auditor Firm ID: 49 Auditor Name: RSM US LLP Auditor Location: Boston, Massachusetts, USA

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PART III

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PART IV

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On November 3, 2023, or the Closing Date, we consummated the previously announced business combination, or the Merger, pursuant to that certain Agreement and Plan of Merger, or the Merger Agreement, dated July 14, 2023, by and among our company (formerly known as Frequency Therapeutics, Inc., or Frequency), Frequency Merger Sub, Inc., or Merger Sub, and Korro Bio Inc., or Legacy Korro.

Pursuant to the terms of the Merger Agreement, a business combination between Frequency and Legacy Korro was effected through the merger of Merger Sub with and into Legacy Korro, with Legacy Korro surviving as a wholly owned subsidiary of Frequency. On the Closing Date, Frequency changed its name to Korro Bio, Inc.

Unless the context otherwise indicates, references in this Annual Report on 10-K to the “Company,” “we,” “our” and “us” refer, collectively, to Korro Bio, Inc., a Delaware corporation, and its consolidated subsidiaries (including Legacy Korro).

We use various trademarks and trade names in our business, including without limitation our corporate name and logo. All other trademarks or trade names referred to in this Annual Report on Form 10-K are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Annual Report on Form 10-K may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K or Annual Report, contains includes statements that are not historical facts and are considered forward-looking statements. We intend such forward-looking statements to be covered by within the safe harbor provisions for forward-looking statements contained in meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended. All amended, or the Exchange Act. Our forward-looking statements include, but are not limited to, statements regarding our or our management team’s expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other than characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intends,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “will,” “would” and similar expressions may identify forward-looking statements, but the absence of historical facts contained these words does not mean that a statement is not forward-looking. Forward-looking statements in this Annual Report on Form 10-K may include, for example, statements about:

- our ability to recognize the benefits of the Merger;
- the initiation, timing, progress, results, and cost of our research and development programs and our current and future preclinical studies and clinical trials, including statements regarding our future the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of operation: trials will become available, and financial position, business strategy, product candidates, clinical development plans and expectations, prospective products, product approvals, our research and development costs, timing programs;
- our strategy;

- our cash runway and likelihood ability to reach data inflection points;
- the therapeutic and commercial potential of success, our product candidates;
- our research and plans development and objectives other expenses;
- our ability to comply with, and the impact of, management for future operations regulatory requirements, obligations and results, restrictions on our business and opera
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others, including our ability to obtain an maintain rights to the technologies required to develop and commercialize our product candidates;
- competitive developments, including the impact on our competitive position of rival products and product candidates and our ability to meet such competition; and
- our ability to manage the growth of our business.

These forward-looking statements are forward-looking statements. These statements involve subject to known and unknown risks, uncertainties and other important factors assumptions about us that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by such forward-looking statements, including those set forth under the heading "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K. Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" Should one or "continue" more of the risks or the negative of these terms or other similar expressions. The forward-looking statements uncertainties described in this Annual Report are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report and are subject to a number of important factors that could cause Form 10-K, or should underlying assumptions prove incorrect, actual results to differ materially from those in the forward-looking statements, including the risks, uncertainties and assumptions described under the sections in this Annual Report titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." These forward-looking statements are subject to numerous risks, including, without limitation, the following:

- the initiation, timing, progress and results of our preclinical and clinical trials and research and development of programs, including our planned Phase 1 study in our remyelination in multiple sclerosis program, and any other future clinical trials for any product candidates;
- our ability to continue to develop our progenitor cell activation, or PCA, approach and identify additional product candidates;
- our ability to successfully complete clinical trials of any product candidate and obtain regulatory approval for it;
- the timing or likelihood of regulatory filings and approvals;
- the commercialization, marketing and manufacture of any product candidate, if approved;
- the pricing and reimbursement of any product candidate, if approved;
- the rate and degree of market acceptance and clinical utility of any products for which we receive regulatory approval;
- the implementation of our strategic plans for our business, product candidates, and technology, including our reduction in force and changes to senior management;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates, PCA approach, and technology;
- estimates of our expenses, future revenues, capital requirements, and our need for additional financing;
- our ability to establish collaborations;
- the impact and any future impact of public health emergencies, such as COVID-19, on our ongoing and planned clinical trials, our research and development activities at our business and financial markets;
- our ability to protect our network from cybersecurity threats;
- our financial performance and the sufficiency of our financial resources; and
- developments relating to our competitors and our industry, including the impact of government regulation.

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Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur, and actual results could differ materially from those projected expressed in the any forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Except as otherwise required by applicable law, we do not plan disclaim any duty to publicly update or revise any forward-looking statements, contained herein, whether as a result all of any new information, future events, changed circumstances, or otherwise.

You should read this Annual Report and which are expressly qualified by the documents that we reference statements in this Annual Report completely and with section, to reflect events or circumstances after the understanding that our actual future results may be materially different from what we expect. date of this annual report. We qualify that all of our forward-looking statements by these cautionary statements.

SUMMARY OF RISK FACTORS SUMMARY

Our business involves significant risks. Below is subject to numerous a summary of the material risks that our business faces, which makes an investment in our securities speculative and uncertainties, including those risky. This summary does not address all these risks. These risks are more fully described below under the heading "Risk Factors" in Part I, Item 1A. "Risk Factors" in 1A of this Annual Report on Form 10-K. You Before making investment decisions regarding our securities, you should carefully consider these risks and uncertainties when investing in our common stock. risks. The principal risks and uncertainties affecting occurrence of any of the events or developments described below could have a material adverse effect on our business, include results of operations, financial condition, prospects and stock price. In such event, the following:

market price of our securities could decline, and you could lose all or part of your investment. Further, there are additional risks not described below that are either not currently known to us or that we currently deem immaterial, and these additional risks could also materially impair our business, operations or market price of our securities.

- We are heavily dependent on have incurred significant losses since inception and expect to incur losses for the success of our remyelination in multiple sclerosis program, foreseeable future and may never achieve or MS Program, which is still under development. If our MS Program does not receive regulatory approval or is not successfully commercialized, our business will be materially adversely harmed; maintain profitability.
- We utilize Expectations regarding our PCA approach cash runway and ability to develop product candidates reach data inflection points are based on numerous assumptions that are designed may prove to activate progenitor cells, which is a new approach to therapeutic intervention and, as a result, successful development, approval, and commercialization of any product candidates, including from our MS Program, is uncertain;
- Clinical trials are expensive, time consuming, and difficult to design and implement, and involve an uncertain outcome. The results of preclinical studies and early clinical trials are not always predictive of future results. Our FX-322 Phase 2b results (FX-322-208), for example, showed no statistically significant difference at day 90 between those administered FX-322 versus those receiving placebo in the proportion of individuals that demonstrated an improvement in speech perception. Any other product candidate that we advance into clinical trials may also not achieve favorable results in later clinical trials, if any, or receive marketing approval; be untrue.
- We may be impacted by general economic, political, required to raise capital sooner than anticipated and geopolitical conditions such as recessions, interest rates, inflation rates, labor shortages, supply chain difficulties, fuel prices, sanctions, our exposure to certain contingent liabilities and acts of war contractual obligations may be greater than anticipated.
- We have never generated revenue from product sales and may never become profitable.
- We will need substantial additional funding. If we are unable to raise capital when needed, we will be forced to delay, reduce, eliminate or terrorism, including the recent hostilities between Russia prioritize among our research and Ukraine. For example, the recent sanctions imposed by the United States on Russia may impede our ability to pay fees related to Russian patents making the development programs or future of such patents uncertain; commercialization efforts.
- The regulatory approval processes of the FDA gene editing field and comparable foreign regulatory authorities RNA editing in particular is relatively new and is evolving rapidly. We are lengthy, time consuming, very early in our research and inherently unpredictable, development efforts and if we are ultimately unable to obtain regulatory approval for our MS Program or any other product candidates, our business will be substantially harmed;
- We may not be successful in our efforts to identify additional identifying and developing product candidates. Due It will be many years before we or any potential future collaborators commercialize a product candidate or generate any revenues, if ever. Additionally, other gene editing technologies may be discovered that provide significant advantages over RNA editing, which could materially harm our business.
- RNA editing is a novel technology that is not yet clinically validated for human therapeutic use. The approaches we take to our limited resources discover and access develop novel therapeutics are unproven and may never lead to capital, we must prioritize development of certain product candidates, the choice of which may be wrong and adversely affect our business; marketable products.
- We will require additional capital to fund are very early in our operations, research and if we fail to obtain necessary financing, we development efforts, and our preclinical studies and clinical trials may not be able successful. If we are unable to complete the development and commercialization of commercialize our MS Program and add product candidates; candidates or experience significant delays in doing so, our business will be materially harmed.
- We face significant competition from biotechnology and pharmaceutical companies and our operating results will suffer if Any product candidates we develop may fail in preclinical or clinical development or be delayed to compete effectively; a point where they do not become commercially viable.
- If we are unable not able to establish sales obtain or protect intellectual property rights related to any of our product candidates, development and marketing capabilities either on commercialization of our own or in collaboration with third parties, we product candidates may be adversely affected.
- The market price of our common stock is expected to be volatile, the market price of the common stock may drop following the Merger and an active trading market for common stock may not develop and our stockholders may not be successful in commercializing any product candidate we develop; able to resell their shares of common stock for a profit, if approved; at all.
- Public health emergencies, including COVID-19, have caused Provisions in our charter documents and under Delaware law could continue make an acquisition of our company more difficult and may discourage any takeover attempts that stockholders may consider favorable, and may lead to cause disruptions to our business, including our preclinical studies, clinical trials and operations and could adversely impact our financial condition and results entrenchment of operations;
- We are currently subject to securities class action and other shareholder litigation and could be subject to similar or other litigation in the future; and management.

- Our **organizational changes undertaken** executive officers, directors and principal stockholders have the ability to **better align** control or significantly influence all matter submitted to our workforce with the needs of our business and focus more of our capital resources on our research and development programs may not achieve our **intended outcome**. stockholders for approval.

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PART I

Item 1. Business.

Overview

We are a biopharmaceutical company with a mission to discover, develop and commercialize a new class of genetic medicines based on editing RNA, enabling the treatment of both rare and highly prevalent diseases.

We are generating a portfolio of differentiated programs that are designed to harness the body's natural RNA editing process to effect a precise yet transient single base edit. By editing RNA instead of DNA, we are expanding the reach of genetic medicines by delivering additional precision and tunability, which has the potential for increased specificity and improved long-term tolerability. Using an oligonucleotide-based approach, we expect to bring our medicines to patients by leveraging our proprietary platform with precedented delivery modalities, manufacturing know-how, and established regulatory pathways of approved oligonucleotide drugs. However, the scientific evidence to support the feasibility of developing product candidates using our RNA editing technology is both preliminary and limited. Moreover, regulators have not yet established any definitive guidelines related to overall development considerations for RNA editing therapies and no clinical data has been generated to date.

The advent of large-scale genome sequencing has progressively revealed causal genetic variation underlying several human diseases, both rare and highly prevalent. Genetic mutations, including single nucleotide variants, or SNVs, implicated in disease have been found to be diverse in nature and can affect the function of genes and their associated downstream biochemical pathways. Data correlating DNA to RNA to disease phenotype have demonstrated that SNVs lead to a loss-of-function or a gain-of-function of the gene. In addition, the majority of SNVs implicated in complex diseases are due to modulation of gene function. By editing SNVs on RNA, we believe we will be able to address unmet patient need by transiently modifying gene function.

As our understanding of genetic drivers of disease has increased, significant advances have been made in technologies designed to introduce specific yet permanent changes at the DNA level to treat diseases. While these DNA editing approaches offer great promise for the treatment of certain rare diseases, they present significant risks from potential permanent adverse "off-target" edits. Additionally, the complex nature of DNA editing drug products presents multiple challenges including lack of efficient delivery to target cells and scalable manufacturing, impeding their application to treat complex highly prevalent diseases of larger patient populations. These potential limitations have spurred exploration of alternative approaches to genetic medicine development, such as RNA editing.

Mammals and other lower species like cephalopods have an endogenous process of modifying single bases on RNA, referred to as RNA editing. RNA editing is a natural physiological process, similar to RNA interference, or RNAi, that occurs in cells, including a mechanism mediated by an enzyme called Adenosine Deaminase Acting on RNA, or ADAR. Our RNA editing approach involves co-opting this endogenous editing system via a proprietary engineered oligonucleotide to introduce precise edits to RNA. We iteratively optimize the editing efficiency of our product candidates using a combination of ADAR biology, chemistry and machine learning expertise. Using this approach, we can edit the transcriptome with high efficiency and specificity. The application of such an approach can provide the ability to alter a SNV and affect biology in meaningful ways.

We have assembled a suite of technologies and capabilities to build our RNA editing platform, Oligonucleotide Promoted Editing of RNA, or OPERA.



We

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OPERA integrates a deep understanding of ADAR biology with expertise in oligonucleotide chemistry, machine learning optimization of oligonucleotides and fit-for-purpose delivery, all of which are **pioneering** expected to enable rapid iteration of our product candidates across therapeutic targets. OPERA relies on the following key components that enable us to generate the proprietary RNA editing oligonucleotides that form the basis of our differentiated product candidates:

- Deep understanding from ADAR biology**, supported by extensive preclinical research using *in vitro* assays and proprietary mouse models as well as the fundamental work of our scientific advisors and founders to elucidate key insights and know-how of ADAR biology. This enables an understanding of ADAR activity

in different species and disease states, allowing us to develop novel product candidates.

- **Expertise in oligonucleotide chemistry**, enabled by the ability to identify and incorporate chemical modifications to generate a **new category** fully modified synthetic oligonucleotide. This increases our ability to generate oligonucleotides with drug-like properties, thereby increasing the editing and translational efficiency of our product candidates.
- **Machine learning optimization of oligonucleotides**, driven by data science and computational capabilities for rapid design and iteration resulting in **regenerative** optimal product candidates for each disease being pursued.
- **Fit-for-purpose delivery**, made possible by tissue-specific delivery technologies that can enhance biodistribution, specificity, durability and editing efficiency of product candidates for each given disease.

Such product candidates include Customized High-fidelity Oligonucleotides for RNA Deamination, or CHORDs™. CHORDs are single stranded, anti-sense oligonucleotides designed to have high target efficiency and specificity by leveraging the pillars of OPERA.

The versatility of RNA editing combined with our OPERA platform broadens the therapeutic target space significantly. While our approach can be used to repair pathogenic SNVs, as demonstrated by our most advanced program, our Alpha-1 Antitrypsin Deficiency, or AATD, product candidate, KRRO-110, we can also engineer *de novo* SNVs and change amino acids on proteins to endow them with desired properties while preserving their broader functional capabilities as exemplified by three of our other programs (sAH, ALS, Pain). In preclinical studies, we have demonstrated that single RNA changes can disrupt protein-protein interactions, prevent protein aggregation, selectively modulate ion channels and activate kinases. These modification approaches can unlock validated target classes that have historically been difficult to drug, enabling us to pursue a broad range of diseases with potentially large addressable patient populations traditionally out-of-scope for other genetic medicine approaches and current traditional drug modalities.

Each of our programs demonstrates the versatility of the oligonucleotide-based ADAR-mediated RNA editing approach to bring additional precision and tunability to address a broad range of rare and highly prevalent diseases.

- **Repairing pathogenic variants**: A SNV that **aims** is a G to **restore** A mutation on DNA, leading to an aberrant amino acid on a protein can be repaired using RNA editing. Such an approach is relevant when the patient population has a spectrum of disease manifestations from mild-to-severe.
- **Disrupting protein-protein interactions**: A single SNV observed in human **function by developing therapeutics that** genetic association studies has the potential to inform how to transiently activate a **person's innate regenerative potential within** protein pathway. We can generate this protein variant transiently using our RNA editing product candidates, thereby engineering a *de novo* SNV.
- **Other target classes**: There are multiple other target classes that can be addressed such as preventing protein aggregation selectively modulating ion channels and activating kinases that have been traditionally hard to leverage for developing medicines.

The pipeline chart below demonstrates the **body through** breadth of indications and applications enabled by our OPERA platform, with an initial focus on four programs that are all wholly-owned. In addition, we have two other wholly-owned programs not reflected in

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the **activation** pipeline chart below: one for an undisclosed target for sAH, and one for a kinase target for cardiometabolic disease. All of **progenitor cells**. Our **lead** our programs are still in the research or preclinical **program** stage of development and their risk of failure is **designed to activate oligodendrocyte precursor cells with the goal of inducing remyelination and potential functional recovery for individuals living with multiple sclerosis, or MS**, high.

Our proprietary approach, called progenitor cell activation, or PCA, uses small molecules to activate progenitor cells within the body to create functional tissue. These progenitor cells, which are similar to stem cells, already **reside in the target tissues in the body and can develop and differentiate into specific cell types within an organ**. We believe this approach provides us the opportunity to pursue multiple proposed indications and develop potential treatments for an array of degenerative diseases throughout the body.

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Our¹ Subject to submission of regulatory filing and authorization to proceed

We continue to make meaningful advancements across our programs, including advancing KRRO-110 towards clinical development. Specifically, KRRO-110 is our first **application of this technology was** development candidate for the **restoration** treatment for AATD that, using our proprietary RNA editing approach, repairs the amino acid codon. This **repair of the cochlea**, endogenous protein has the potential to clear protein aggregates from within liver cells to create a potentially disease-modifying clinically differentiated benefit for liver function and to preserve lung function by providing an adequate amount of normal AAT protein. AATD is an inherited genetic disorder that can cause severe progressive lung and liver disease due to a lack of normal alpha-1 antitrypsin protein, or AAT, caused by SNV mutations in the SERPINA1 gene. There are an estimated 3.4 million individuals with deficiency allele combinations worldwide. Despite being minimally effective and not fully addressing the needs of many AATD patients, augmentation therapy currently represents approximately \$1.4 billion in annual sales worldwide. KRRO-110 has the potential to elevate the standard of care and expand the number of patients on treatment and potential to be a leader with a **focus on treating** large market opportunity worldwide. However, we have yet to conduct any human clinical trials, our product candidate is in early stages of development and there is no guarantee we will be successful.

KRRO-110 is a condition called sensorineural hearing loss, proprietary oligonucleotide that utilizes a proven lipid nanoparticle, or SNHL, which is LNP, based delivery system administered intravenously to transiently restore production of normal AAT in liver hepatocytes. By correcting the most prevalent type of hearing loss. Our lead cochlear regeneration program, FX-322, was designed pathogenic G to treat the underlying cause of SNHL by regenerating cells A SNV in the inner ear required for hearing through the activation of progenitor cells already present in the cochlea. Since 2019, SERPINA1 gene, we ran five FX-322 clinical studies, all aim to bring individuals with the aim Z mutation to a phenotype where over 50% of understanding safety RNA has been corrected to produce normal AAT protein, preserving lung and liver function and preventing further damage. However, this delivery system has not yet been finalized and, while LNPs have been validated clinically to deliver oligonucleotides, such as well siRNA, they have not been clinically proven to deliver oligonucleotides for RNA editing, such as severities our product candidates.

We believe our approach for treating AATD has multiple potential advantages:

- Provides a disease modifying therapy for both lung and etiologies liver manifestations by transiently editing over 50% of RNA transcripts in hepatocytes to restore normal AAT protein
- Provides a treatment option that FX-322 might treat and can be tailored to address the appropriate dose regime. In several broad spectrum of these studies, we had observed that severity within the AATD population
- Potential to enable physiologic regulation of AAT using endogenous ADAR, thereby increasing normal AAT production during inflammation
- Fit-for-purpose delivery using a single dose proven LNP to maximize editing efficiency, leading to greater potential clinical benefit

We have generated compelling preclinical data demonstrating proof of FX-322 was associated concept across multiple RNA editing oligonucleotides targeting the SERPINA1 gene, including KRRO-110.

- KRRO-110 has achieved high editing efficiency *in vitro* (>50% editing in hepatocytes).
- KRRO-110 demonstrated high specificity with statistically significant improvements no bystander effects in hearing function MZ human primary hepatocytes.
- Intravenous administration of KRRO-110 at 2mg/kg in a human transgenic PiZ mouse model resulted in secretion of approximately 50uM total AAT protein as measured improved speech perception early as seven days post-single dose.
- KRRO-110 increases the expression of normal AAT protein to >70% of total AAT protein in subjects with SNHL giving us confidence circulation in the potential of FX-322 as a potential drug candidate for hearing loss. *vivo*.

In 2021 we commenced our sixth study, a Phase 2b clinical trial of FX-322 (FX-322-208), a randomized, placebo-controlled, multi-center study designed to evaluate the impact of a single administration of FX-322 on speech perception in 124 subjects, ultimately enrolling 142 subjects, with either noise-induced or sudden SNHL, the same hearing loss severities and etiologies as those subjects in which statistically significant improvements in speech perception were observed in prior FX-322 clinical trials. The study's primary endpoint was speech perception, a measure of sound clarity and understanding speech. In a Type-C meeting, the FDA agreed that speech perception is an acceptable primary efficacy endpoint.

For the statistically powered study, we assumed 5% of placebo subjects would show an improvement. Therefore, our treatment effect was targeted to be 20% at day 90. Consequently, a sample size of 112 subjects at 80% power to detect this 20% difference at a significance level of 0.05 resulted in enrollment of 142 subjects to account for potential subject attrition.³

In February 2023, we announced results

An increase in functional AAT protein with the inhibition of elastase activity was sustained through week nine when KRRO-110 was dosed every two weeks, demonstrating durability in mice.

- Engineered surrogate oligonucleotides that edit RNA at an adjacent site on the Phase 2b clinical trial SERPINA1 gene relative to KRRO-110 have high translation of FX-322-208) and that RNA editing efficiency from mice to non-human primates, or NHPs, demonstrating the study failed to achieve its primary efficacy endpoint of an improvement in speech perception. Data showed no statistically significant difference at day 90 between those administered FX-322 versus those receiving placebo in proportion of individuals that demonstrated an improvement in speech perception. There were also no measurable improvements observed in any of the study's secondary endpoints. As a result of this outcome, we decided to discontinue the FX-322 development program.

Simultaneously, we were working on a second hearing program, called FX-345, which we believed might expand the opportunity to treat different types of SNHL. FX-345 was designed to achieve exposure at desired drug concentrations through a large portion of the cochlea. Cochlear pharmacokinetic measures and human model data in a preclinical setting showed that FX-345 achieved exposure at desired concentrations through a larger portion of the cochlea for longer time as compared to FX-322, and therefore we believe that greater coverage of the cochlea using FX-345 may extend the reach potential applicability of our approach. The FX-345 program commenced dosing approach in a Phase 1b study completing an initial safety cohort. Given the outcome of the FX-322-208 study data and the similarities of the two candidates in design, intended mechanism of action and clinical design components, the decision was made to also cease development of FX-345 and our hearing program overall now focus our resources to advance the remyelination in MS program, or MS Program, into the clinic. humans.

While exiting hearing was a difficult decision, we continue to strongly believe our PCA approach we can impact a wide range of degenerative diseases. We are now working to rapidly advance discovery efforts using our PCA approach to potentially remyelinate neurons in individuals with MS. MS induces demyelination, stripping axons demonstrate many of the myelin sheaths that support neuronal signal conduction key advantages of RNA editing, we are very early in our development efforts and axonal survival. We previously reported that we had identified a novel target relevant to myelination. Modulation of this target induces robust oligodendrocyte differentiation and expression of myelin proteins in vitro. We have identified multiple novel chemical entities that induce robust remyelination following demyelination in an adult in vivo animal model.

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The MS Program is independent not yet certain of the now discontinued hearing program, with results we may achieve. Such uncertainties include, but are not limited to, the level of editing efficiency needed in a distinct molecular target mechanism, progenitor cell population, tissue type to achieve a clinical benefit, and small molecule drug candidates. Further, associated safety of our edits in humans. Preclinical development of KRRO-110 is ongoing in preparation for a well-defined clinical path with objective biomarkers such as visual evoked potential (VEP) and magnetic resonance imaging (MRI) exist for studying the performance of remyelination therapies in MS patients. Our novel agents substantially outperform other clinically studied remyelination agents in head-to-head in vivo studies. We plan to begin our clinical program for remyelination in the first half of 2024. Refer to Our multiple sclerosis (MS) program below for detailed information on our internal program and ongoing sponsored research.

Concurrent with the release of the FX-322 Phase 2b clinical trial (FX-322-208) results in February 2023, the Company also announced it will immediately reduce headcount as part of an overall restructuring, downsizing personnel by approximately 55 percent. The Company believes that the restructuring will generate sufficient cost savings to extend its runway into 2025 and enable it to complete a first clinical trial of its MS Program regulatory filing in the second half of 2024. 2024, and an anticipated interim clinical readout in the second half of 2025.

Our team and historyTeam

We were launched in 2018 and were co-founded by Nesson Bermingham, Jean-Francois Formela, Joshua Rosenthal and Andrew Fraley. Our science was based on pioneering research from the laboratory of Joshua Rosenthal, Ph.D., at the Marine Biological Laboratory, or MBL in Woods Hole, Massachusetts. Dr. Rosenthal's work includes landmark discoveries in RNA editing based on adenosine deamination.

Our company was founded We are led by an experienced team with deep expertise in 2014 with the goal genetic medicines, development of creating medicines based on breakthrough research focused on activating the body's regenerative potential. oligonucleotide-based therapeutics, building novel therapeutic platforms, and bringing multiple therapeutics to market. In their groundbreaking research, Professors Robert S. Langer at the Massachusetts Institute of Technology and Jeffrey Karp at Harvard Medical School decoded the natural signals between cells that make the intestine one of the most regenerative organs in the body through the continuous activation of progenitor cells. Recognizing that similar progenitor cells were present but inactive in other organs, they discovered how to adapt these natural signals using small molecules to temporarily activate progenitor cells in other organs and create a localized healing response.

Our addition, our executive leadership team includes experienced has a successful track record of company building and leading biotech executives David L. Lucchino, our companies, including Ram Aiyar, Ph.D., President and Chief Executive Officer, an experienced executive and co-founder, Christopher R. Loose, our company builder with 20 years of diverse industry experience including research, business and strategy; Steve Colletti, Ph.D., Chief Scientific Officer, who brings nearly 30 years of drug discovery and co-founder, development experience covering a broad range of therapeutic areas and Quentin McCubbin, our modalities; and Vineet Agarwal, Chief Manufacturing Officer. As Financial Officer, who brings more than 14 years of financial and industry experience as a result of our restructuring, Carl P. LeBel, Chief Development Officer, and Wendy S. Arnold, Chief People Officer, will be leaving the Company effective March 31, 2023 while Susan Stewart, Chief Regulatory Officer, will be leaving the Company effective April 30, 2023. biotech investment banker with J.P. Morgan Chase & Co. We also have also assembled a world-class team of leaders in regenerative biology, drug development, and drug delivery with a Remyelination Advisory Board an accomplished scientific advisory board comprised of leading experts from across in the neurosciences. Our PCA Regenerative Medicine Advisory Board members fields of ADAR biology, chemistry, translation medicine, and nucleic acid therapeutics.

We are at the forefront a mission-driven organization and thrive through a strong culture of scientific discovery innovation and behavior that embodies our core values and principles. We are actively working to rewrite the future of medicine by remaining on the activation cutting edge of progenitor cells science and their potential application research. We believe our success is enabled by working better together and embracing diversity, leading us to therapeutic interventions in diseases of multiple tissues employ a dynamic team with varied expertise, enabled by kindness and organs.integrity.

We have attracted a talented team of industry experts and experienced scientists as part of a high-performing, nimble organization. Our research and development organization is comprised of individuals with expertise in DNA editing technologies, liver biology, CNS biology, medicinal chemistry, biochemistry and drug delivery, translational medicine and conducting preclinical studies.

Since inception, we have raised \$343 million in capital, including \$117 million as part of the pre-closing financing that closed immediately prior to the Merger, or the Pre-Closing Financing, from premier venture capital funds, healthcare-dedicated funds, major mutual funds and other leading investors that share our vision of creating transformative genetic medicines for diseases with high prevalence.

Our strategyStrategy

We intend Our mission is to create discover, develop and commercialize therapeutics to potentially transform a new class of RNA editing therapies capable of improving the lives of individuals patients with rare and highly prevalent diseases. We do this by repairing applying our proprietary RNA editing platform, OPERA, which combines our unique expertise in ADAR biology and oligonucleotide chemistry with machine learning-driven optimization and fit-for-purpose delivery. Our RNA editing product candidates are designed to

harness the body's natural RNA editing processes to make a precise single base edit. However, this has only been observed in preclinical studies as we have yet to submit an investigational new drug application, or reversing damage done IND, to cells, tissue, the U.S. Food and organs. To do so, we are implementing Drug Administration, or FDA, or commence a clinical trial. Our goal is to develop a portfolio of RNA editing product candidates with best-in-class properties across a range of diseases by executing on the following strategies: key pillars of our strategy:

- **Advance Develop a remyelination therapy novel class of RNA editing therapies using our PCA approach. learnings from a combination of genetics and approved medicines.** We believe are leveraging significant advances in the understanding of the correlation between DNA, RNA and disease phenotypes to develop novel therapeutic approaches across a range of validated biological targets. This novel class of RNA editing therapeutics combines the precision of genomic therapies with the properties associated with traditional approved drugs, such as titratability and ability to re-dose. In addition, our PCA approach RNA editing product

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candidates are structurally similar to other clinically and commercially validated drug modalities such as antisense oligonucleotides, or ASOs, and small-interfering siR conferring potential advantages in manufacturing, regulatory review and clinical adoption.

- **Develop and advance into the clinic a differentiated disease-modifying therapy for patients with AATD.** Our first development candidate, KRRO-110, has the potential to address provide a wide range of clinical applications. We will continue to invest in research differentiated therapeutic option for AATD by addressing both the liver and development to enhance our PCA approach with the goal of delivering new therapeutics in additional indications. We identified MS as a disease where PCA has the potential to produce a restorative effect by stimulation of oligodendrocyte precursor cells, or OPCs, to myelinate axons. We established an internal research program using PCA to induce remyelination as a potential therapy for MS and lung pathologies. Our RNA editing oligonucleotide product candidates, including KRRO-110, have generated several compelling preclinical stage compounds data that based on demonstrates restoration of normal AAT protein while preventing the aggregation of dysfunctional AAT in the liver. Our preclinical *in vivo* models, have shown significantly greater remyelinating effect than published comparator approaches. Our efforts are focused on advancing these compounds data has demonstrated durability and high editing efficiency in preclinical safety studies to enable both mice and NHPS, illustrating the potential applicability in humans. Preclinical development of KRRO-110 is ongoing in preparation for a first human trial to begin potential regulatory filing in the first second half of 2024, 2024, and an anticipated interim clinical readout in the second half of 2025. Depending on the evidence of efficacy and tolerability, we intend to pursue expedited regulatory pathways. However, regulators have not yet established any definitive guidelines related to overall development considerations for RNA editing therapies and no clinical data has been generated to date.
- **Deploy our versatile OPERA platform to develop a portfolio of programs that modify proteins transiently to expand into highly prevalent diseases.** OPERA has the ability to generate unique RNA editing therapies that can modify protein function or endow proteins with engineered changes that will potentially result in desirable properties to treat disease. In preclinical studies, we have demonstrated that single RNA changes can disrupt a protein-protein interaction, prevent protein aggregation, selectively modulate an ion channel and selectively activate a kinase. These modification approaches can unlock validated target classes that have historically been deemed undruggable, enabling us to pursue a broad range of diseases, including those with high prevalence. We are evaluating potential applications of our OPERA platform for use in other highly prevalent indications including the central nervous system, or CNS, liver, and cardiometabolic therapeutic areas.
- **Continue to build strategic collaborative relationships optimize and enhance our OPERA platform..** Given the broad potential opportunity We believe we have built a leading RNA editing company through a combination of our PCA OPERA platform, intellectual property strategy and human capital. Our computationally driven approach we believe entering into strategic research, development, enables rapid design and commercial collaborations in select therapeutic areas may provide an attractive avenue to facilitate the capital-efficient optimization of potential oligonucleotide product candidates. In development of our PCA approach AATD program, we were able to go from "design-to-data" in 5-6 weeks. We intend to continue to incorporate new data into these machine learning models to improve their ability to predict editing efficiency and product pipeline. We believe these strategic collaborations could potentially provide significant funding to advance our more expeditiously optimize and nominate new product candidates, while allowing us to benefit from the although there is no guarantee that this will result in an accelerated development and therapeutic area expertise of our collaborators. We may collaborate with large pharmaceutical companies, biotechnology companies, and academic institutions to maximize or approval timeline, if at all.
- **Maximize the potential of our PCA approach OPERA platform through collaborations and strategic partnerships.** We currently retain worldwide development and commercialization rights to create new therapies for patients, our programs and platform. We actively collaborate with clinical leaders, academic medical centers of excellence, and patient advocacy groups to continue to enhance our expertise in our focus therapeutic areas. Given the versatility and broad potential of our OPERA platform across therapeutic areas, especially in diseases with high prevalence, we may enter into strategic partnerships with external parties that have complementary capabilities to broaden and accelerate access to our RNA editing therapies.
- **Invest in human capital and encourage innovation to maintain a leading position and advance the frontiers of genetic medicines.** We are a mission-driven organization, and we thrive through a strong culture that embodies our core values. We are actively working to rewrite the future of medicine and remain on the cutting edge of science and research by working better together and embracing diversity in employing a dynamic team with varied expertise, enabled by kindness and integrity. We have attracted a talented team of industry experts and experienced scientists as part of a high-performing and nimble organization. Our research and development organization is comprised of individuals with expertise in editing technologies, RNA biology, liver biology, CNS biology, medicinal chemistry, biochemistry and delivery, translational medicine, preclinical and clinical development.

Expanding the Frontiers of Genetic Medicines: RNA Editing

The advent of large-scale genome sequencing has progressively revealed causal genetic variation underlying several human diseases, both rare and highly prevalent. Genetic mutations, including SNVs, implicated in disease have been found to be diverse in nature and can affect the function of genes and their associated downstream biochemical pathways. Natural genetic variations, revealed by population-level genomic studies, have also been shown to protect against or to increase the risk of disease. Beyond these developments, groundbreaking advances in gene therapy, cell therapy and RNA therapeutics have resulted in several approvals that have transformed the treatment of certain genetic diseases and cancers as well as the prevention of infectious diseases, such as COVID-19. In addition, various DNA editing approaches have been developed that introduce specific genetic changes to DNA to treat diseases. First generation CRISPR-Cas9 DNA editing has demonstrated the potential to knockout

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pathogenic mutations at the single gene level with several programs in clinical development and the first *ex vivo* DNA editing therapeutic for a rare hematological condition on file at the FDA. Next generation DNA editing approaches have recently entered the clinic and hold the promise to edit DNA at the single nucleotide level.

Despite these advances, significant risks exist with DNA editing approaches. A key concern is the introduction of unwanted DNA modifications ("off-target" edits) which could have permanent adverse effects such as chromosomal integration and non-specific insertions, deletions and substitutions. Additionally, due to the complexity of a multicomponent DNA editing product, delivery to target cells can be challenging and even more so if there is a need to edit multiple genetic loci. Furthermore, manufacturing is highly complex and expanding to commercial scale remains challenging, specifically for a highly prevalent indication. Given these challenges, DNA editing approaches will likely remain a focus for certain rare diseases, while its ability to treat diseases of high prevalence continues to be limited.

ADAR-mediated RNA editing

RNA editing involves altering a sequence of RNA which intrinsically has the potential to address some of the limitations of DNA editing. RNA editing mediated by adenosine deaminase acting on RNA, or "ADAR-mediated" RNA editing, has recently emerged as a differentiated approach that can generate product candidates having features that combine the precision of genomic therapies with the properties commonly associated with current approved drugs such as titratability and ability to re-dose. Importantly, these drug-like characteristics enable ADAR-mediated RNA editing candidates to be potentially safer and target diseases with high prevalence that would be difficult for DNA editing approaches to address.

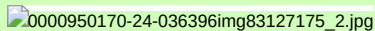
ADARs are a family of enzymes present inside a cell, that bind RNA. ADARs bind double-stranded RNA structures, and convert a single base of adenosine (A) on RNA, into an inosine (I) that is typically translated as a guanosine (G), using an enzymatic process. ADAR mediated editing is found at high levels in cephalopods both on the coding and non-coding regions of the RNA. In humans, there are fewer recoding events, and most of the endogenous editing events occur in non-coding regions.

Humans have two known active endogenous ADAR enzymes, ADAR1 and ADAR2. ADAR1 is constitutively expressed and is present in most tissues within the body, whereas ADAR2 is more highly expressed in tissues such as the brain. The ADARs are essential enzymes for normal physiologic function. ADAR-driven RNA editing has been found to be critical for the function of a number of proteins, such as the glutamate ionotropic receptor, which has been found to be almost always RNA-edited in humans. Given ADARs' natural function to catalyze A-to-I edits, this endogenous editing system can be leveraged to make programmed edits to RNA. This ability to introduce programmed highly targeted edits into RNA has the potential to expand the reach of genetic medicines with an ability to modify proteins to achieve a desired function.

Oligonucleotide-based ADAR-mediated RNA Editing

There are multiple therapeutic approaches to utilize ADAR-mediated RNA editing, including synthetic oligonucleotides, engineered ADARs, and Cas-based editing approaches. Our therapeutic approach delivers oligonucleotides to target tissues and cells to introduce precise edits to RNA through recruitment of endogenous ADAR.

Normally, ADARs are recruited to target RNA editing sites through recognition of specific double-stranded RNA structures such as naturally occurring hairpins or loops in endogenous transcripts. Importantly, one can mimic these double-stranded RNA structures by introducing complementary synthetic oligonucleotides into cells. An oligonucleotide can be engineered to mimic the double-stranded RNA structure such that endogenous ADAR is recruited. Using this targeted approach, a site directed specific A-to-I edit can be introduced.

Our approach: Progenitor cell activation within the body 

We are pioneering a new class of small molecule therapeutics designed to activate progenitor cells already present within the body to create healthy functional tissues and organs. We developed RNA editing using our PCA approach to identify small molecules that selectively activate progenitor cells to regenerate tissues. Our current therapeutic focus is remyelination in MS. We believe that our preclinical studies in MS have validated the potential of our PCA approach to provide a new methodology to regenerative medicine. proprietary platform

Relationship between stem cells and progenitor cells

All cells in the human body arise from Key Advantages of Oligonucleotide-Based ADAR-Mediated RNA Editing as a single unspecialized, or undifferentiated, cell type called a pluripotent stem cell. Two of the key characteristics of pluripotent stem cells are their ability to renew themselves through cell division and the ability to differentiate into any cell type. Progenitor cells have similar self-renewal properties as pluripotent stem cells. However, progenitor cells are programmed to develop and differentiate into specific cell types within an organ. The progenitor cells are programmed to create specific cell types and, in some cases, allow mature tissue and organs to repair and renew. However, researchers have discovered that many organs throughout the human body that do not spontaneously regenerate do contain inactive progenitor cells that, if stimulated, are potentially available to induce regeneration.

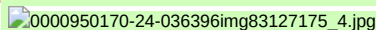
Therapeutic Modality

We believe that oligonucleotide-based ADAR-mediated RNA editing is a groundbreaking technology that is ideally suited to expand the application of genetic medicines for indications that DNA editing is unable to address. Over the last two decades, there has been significant research around and development of oligonucleotide-based therapeutics, including modalities such as siRNA and ASOs, that has led to the approval of multiple drugs. Specifically, developments in oligonucleotide chemistry, delivery technologies, tolerability, and manufacturing, combined with better defined regulatory pathways, have led to the approval of oligonucleotide-based therapeutics specific for multiple different tissue types. We differentiate our PCA approach bypasses from DNA-editing by leveraging the challenges presented by stem cell know-how from approved oligonucleotide therapies by utilizing small molecule therapeutics to temporarily reactivate progenitor cells that are already located at the tissue target site within the body and are pre-programmed to make specific cell types. in development of our product candidates.

Key attributes of our PCA approach

Our discoveries in regenerative medicine allow us to activate While we believe we can demonstrate many of the innate capabilities of progenitor cells. We believe our PCA approach represents a transformative step in the evolution of regenerative medicine by providing the following key advantages compared of RNA editing, we are very early in our development efforts and not yet certain of the results we may achieve. Such uncertainties include, but are not limited to other regenerative approaches: the level of editing efficiency needed in a target tissue type to achieve a clinical benefit, and associated safety of our edits in humans.

- **Harnesses innate biology Specificity.** We overcome the major challenge of delivering and integrating cells into the proper location within tissue. Our small molecule therapeutic candidates activate the body's own progenitor cells : Oligonucleotide-based ADAR-mediated RNA editing enables highly precise edits at the desired location in targeted tissues.
- **Ease target single nucleotide level on the RNA with low risk of manufacturing.** We eliminate off-target or bystander edits, addressing a key safety concern associated with other DNA editing approaches that carry the need to remove risk of permanent insertions and grow live cells ex vivo, which deletions as well as chromosomal integration. Using synthetic oligonucleotides, appropriate chemical modifications can be costly introduced to increase the overall specificity and complex to manufacture and may pose potential safety risks. In contrast, our small molecule therapeutic candidates will be produced using standard pharmaceutical manufacturing methods.
- **No change to genome.** Instead of altering genes, our small molecules targeting efficiency for the site directed RNA editing. The OPERA oligonucleotides are designed to temporarily activate be highly site selective with minimal to no bystander effects or halo effects. To assess global off-target editing, we use a bulk RNA-seq approach to detect base frequency changes at potential off target sites between control and treated samples. We sequence target amplicons via NGS and assess potential A to G editing at all sites across the biochemical pathways transcript. In preclinical in vivo studies, we have shown that play a central role in the development of organs off-target RNA editing using our technology is negligible and tissues. This small molecule approach could create a disease-modifying or restorative effect without changing the body's genetic code. In addition, we believe we avoid the risk of acquiring immune reactivity to our therapeutics, which is commonly associated with genetically modifying cells. transient.



Our therapeutic discovery process

We utilize a proprietary process to identify small molecule combinations for activating progenitor cells.

- **Discovery in the right context.** Traditional drug screening uses immortalized cell lines that are convenient for use in a laboratory but may not reflect the complex biology of tissue-specific cell types in the body. One of our core capabilities is using primary progenitor cell assays that are designed to maintain these cells in their natural state in order to increase the likelihood of successful drug discovery and translation into an effective tissue-specific therapeutic.
- **Decoding and controlling activation pathways for progenitor cells.** We use our accumulated insights into progenitor cell signaling and aging to identify biological pathways that may activate a specific progenitor cell. We then design and apply small molecules to modulate the chosen biological pathways and achieve PCA.

By assessing our small molecule combinations in a highly relevant context, we and our collaborators have applied this discovery process to identify compounds that activate progenitor cells in numerous tissues.

Our multiple sclerosis (MS) program

Figure 2. Overview of off-target editing observed in mice across multiple sclerosis oligonucleotides

The symptoms of MS include numbness or tingling, weakness, dizziness and vertigo, spasticity, vision problems, sexual problems, bladder or bowel problems, pain, cognitive changes, emotional changes, and depression. Initially, most individuals experience a relapsing-remitting experience course of disease, with periods of new or relapsing symptoms followed by recovery and periods of remission. Early in the disease course, the individuals are partially able to remyelinate the demyelinated nerves. As the disease progresses the ability of the body to remyelinate axons significantly decreases leading to progressive and irreversible neurological deficits. According to the National Multiple Sclerosis Society, nearly one million people in the United States are living with MS.

The FDA has approved a number of disease-modifying therapies for MS that reduce the immune system attack on myelin, which may reduce the number of relapses, delay progression of disability, and limit new disease activity. However, none of these products directly induce the remyelination of the nerve fibers. There are no FDA approved remyelinating therapies for MS and we believe this remains the largest unmet medical need in individuals with MS. Our program aims to induce OPCs to differentiate into oligodendrocytes and replace the myelin lost to multiple sclerosis.

Our novel compounds

We believe our PCA approach can impact a wide range of degenerative diseases, including MS. MS induces demyelination, stripping axons of the myelin sheaths that support nerve signal conduction and axonal survival. Our program focuses on inducing remyelination by activating oligodendrocyte progenitor cells, or OPCs, in the central nervous system to generate new oligodendrocytes and regenerate myelin, potentially repairing the damage caused by MS. Our efforts are focused on advancing proprietary Frequency compounds in preclinical safety studies to begin our clinical program in the first half of 2024.

The potential for pharmacologic therapy to induce remyelination in MS has been supported by multiple clinical trials. Clinical trials testing clemastine, histamine receptor 3 inverse agonists, anti-LINGO antibodies, and bexarotene have shown modest improvements in electrophysiological or MRI measures of MS.

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- **Delivery:** Oligonucleotide-based ADAR-mediated RNA leverages well established, clinically precedented delivery approaches used in other approved products, such as LNPs and ligand-based approaches. LNP-based delivery of oligonucleotides is a well established and clinically validated delivery approach that provides sustained targeted delivery and editing efficiency, resulting in infrequent dosing and an acceptable tolerability profile. Additionally, LNP delivery of RNA-editing oligonucleotides enhances optimal distribution to targeted cells. One example of a well-established and clinically validated ligand-based delivery approach is GalNAc delivery of oligonucleotides, which provides highly specific and effective delivery to hepatocytes with improved durability.
- **Tolerability:** ADAR-mediated RNA editing has a low risk of immunogenicity and can potentially lower off-target editing events resulting in an improved tolerability profile compared to DNA editing approaches. The lower risk of immunogenicity enables the ability to re-dose patients if required, a significant limitation of editing approaches that utilize viral vectors and bacterial Cas systems that carry a higher risk of immunogenicity. The transient and reversible nature of ADAR-based editing confers an ability to modify or cease dosing as needed.
- **Manufacturing:** Reliance on endogenous ADAR enzymes and the simple drug constructs of oligonucleotide-based therapies has significant advantages over the complexities associated with the manufacturing and delivery of multi-component exogenous complexes used in DNA editing. Manufacturing processes for oligonucleotide-based therapies are well established, cost efficient and scalable to effectively address highly prevalent indications.
- **Regulatory:** Precedence of marketed oligonucleotide drugs with similar size and types of chemical modifications that therapeutic RNA editing product candidates exhibit. Guidance for the development of oligonucleotide therapeutics by global agencies, including the FDA, provides for an established pathway for the approval of this class of therapeutics. However, regulators have not yet established any definitive guidelines related to overall development considerations for RNA editing therapies and on clinical data has been generated to date.

Our OPERA – Oligonucleotide Promoted Editing of RNA – Platform

We believe we are the leading RNA editing company and have assembled a suite of technologies and capabilities called OPERA, Oligonucleotide Promoted Editing of RNA, to generate differentiated RNA editing product candidates, or CHORDs. A key challenge in developing a therapeutic approach for site-directed RNA editing is to design and optimize oligonucleotides that can drive high-efficiency. This efficiency is facilitated both by the ability to repurpose and optimize oligonucleotide constructs based on existing methods as well as utilizing computational methods to innovate on chemistry and design of the constructs. Our RNA editing product candidates are oligonucleotides capable of forming Watson-Crick base pairing with the target RNA and efficiently inducing the deamination reaction by endogenously recruiting ADAR enzymes.

We have assembled a suite of technologies and capabilities to build our RNA editing platform, Oligonucleotide Promoted Editing of RNA, or OPERA.

OPERA relies on the following key components that enable us to generate our differentiated RNA editing product candidates:

- **Deep understanding from ADAR biology:** Our insights and know-how of ADAR biology allow us to design oligonucleotides that efficiently recruit ADARs and promote deamination while maintaining selectivity and stability. RNA editing is dependent on endogenous ADAR expression levels and requires a deep understanding of the physiological role of ADAR, its cell and tissue distribution, the factors that lead to efficient recruitment of ADAR to targeted sites and any consequences that may arise from co-opting ADAR from its normal function. We have developed a cell-free *in vitro* RNA editing assay with purified human ADAR1 and ADAR2 that predicts

the RNA editing activity with our oligonucleotides. With our cell free assay capability, we are able to limit the number of components implicated in screening (target gene, RNA editing product candidates and ADAR), allowing us to measure the kinetics of RNA editing more accurately. Using only three components including the target RNA, oligonucleotide, and ADAR, we have shown that target editing efficiency is correlated with the chemical modification pattern of an oligonucleotide. Furthermore, we have found that this activity predicts the rank order of oligonucleotides in both *in vitro* cell-based systems and *in vivo* in rodents. This assay capability supports our understanding of the key steps required to edit RNA at a level of detail that is not possible in cells. These platform biology assay capabilities have enabled detailed mechanistic studies into the tissue distribution and subcellular localization of ADAR proteins and our RNA editing product candidates.

We have found no evidence that our RNA editing oligonucleotides interfere with endogenous RNA editing occurring naturally in a cell. ADAR naturally edits thousands of targets for a variety of reasons. We have looked at natural editing sites and chose AJUBA, COG and COPA as they have shown to be edited by ADAR to different degrees. In this experiment outlined in Figure 3, ZZ HLC cell lines were transfected with RNA editing product candidates targeting two different genes. The assays were evaluated for % editing for Target A and Target B sites as well as natural editing sites in COG, COPA and AJUBA. As shown below, natural editing sites remained unaffected

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compared to the control group, demonstrating that our RNA editing product candidates are not likely to have any effect on the degree of editing of native RNA molecules



However, Figure 3. Our RNA editing product candidates show no evidence of interference with endogenous ADAR editing as demonstrated at the above endogenous sites

Expertise in oligonucleotide chemistry: We have a differentiated ability to maximize create oligonucleotide designs capable of efficiently recruiting endogenous ADAR with chemical modifications that direct high specificity editing. Our oligonucleotides increase the benefit to individuals with MS, we believe it is likely that significantly more effective remyelinating agents will be necessary. To create such a therapeutic, we established an independent internal research program to explore potency and durability of ADAR activation, thereby increasing the biology underlying remyelination editing efficiency and develop novel chemical entities, or NCEs, translational efficacy of our product candidates. We have identified critical structural, sequence, and chemistry requirements for our product candidates that drive efficient recruitment of ADARs and subsequent A-to-I editing. Examples of differentiation include oligonucleotide length for efficient ADAR recruitment, use of unprecedented and proprietary chemistries within the oligonucleotide, as well as backbone chemistries that provide improved metabolic stability. Additionally, we combine this with 2' modification chemistries that, together, create oligonucleotides with improved editing efficiency and durability. As RNA editing is an emerging technology, there is a lack of guiding principles to design site-selective RNA editing oligonucleotide product candidates. To address this knowledge gap, we developed a robust in-house process using our high-throughput cell-based assay and machine learning capabilities to design and synthesize up to approximately 1,200 oligonucleotides per month and generate up to 6,000 assay data points for any given target.

Machine learning optimization of oligonucleotides: We have built data science capabilities and a dedicated team to extract lessons from existing and newly generated experimental data to expeditiously design and optimize RNA editing product candidates. Our proprietary machine learning models have been trained to accurately predict oligonucleotide structure and observed levels of editing. We have been able to demonstrate that these models are pursuing able to make accurate editing predictions even for previously unseen chemical modifications demonstrating their generalizability across targets. We have demonstrated the utility of our machine learning models through an increase in overall editing efficiency of new product candidates over the last several quarters. In some cases, we have been able to go from design-to-data in as little as five weeks. However, there is no guarantee that this will result in an accelerated development or approval timeline, if at all.

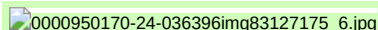


Figure 4. We have shown our ability to rapidly iterate product candidates to maximize editing efficiency

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Structural modeling is another tool that complements our ability to increase the efficiency of our RNA editing candidates. Detailed structural modeling includes shape, size and orientation requirements that can lead to successful deamination at the editing site. These aspects have an important impact on our ability to optimize RNA editing product candidates. As an example, a novel modification predicted by structural analyses led to a conformational change that was shown to improve editing efficiency in the coding region of the Target A *in vivo*.

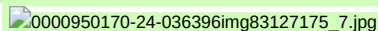


Figure 5. We have demonstrated ability to improve editing in target that modulates oligodendrocyte differentiation coding regions

Fit-for-purpose delivery: Our product candidates utilize short synthetic oligonucleotides, which we believe can be efficiently delivered using technologies such as LNP or GalNAc. These delivery technologies are well established and remyelination. Our internal discovery efforts clinically validated and have yielded been developed for precedented modalities such as siRNAs and ASOs. Each of these delivery vehicles has optimal characteristics suited for a number given therapeutic application. Using CHORDs, we achieved greater than 50% editing *in vivo* utilizing both a ligand-based GalNAc conjugate and an LNP-based delivery approach (see Figure 6).

Additionally, LNP mediated delivery of potential Novel Chemical Entities (NCEs) RNA editing product candidates provides sustained delivery and an acceptable tolerability profile that have shown encouraging remyelination inducing activity been manufactured at a scale sufficient to serve the target population. In addition to LNP based delivery approach, ligand-based approaches (ex., GalNAc for liver hepatocytes) can also be used for effective delivery and to improve durability with OPERA's RNA editing product candidates, which we have also evaluated in preclinical studies. We compared some of our internally discovered preclinical stage compounds to three known compounds, thyroid hormone, anti-LINGO antibody, and clemastine, in in vivo models. In these models, contrast to treatments targeting liver hepatocytes where there is a need for a delivery system, our internally discovered RNA editing product candidates have been delivered intrathecally to the central nervous system without a need for any delivery system in preclinical stage compounds induced significantly more oligodendrocyte differentiation (Exhibit 1) mouse models. Thus, our choice of delivery system is a fit-for-purpose model that is dependent on the oligonucleotide design as well the suitability for the indication and remyelination (Exhibit 2) in vivo than tissue localization of the published comparator compounds. Our internally discovered preclinical stage compounds were shown target. However, this delivery system has not yet been finalized and while LNPs have been validated clinically to be effective even in aged animals and drove remyelination in both white and gray matter, which are critical in motor, sensory and cognitive aspects of MS. deliver oligonucleotides, such as siRNA, they have not been clinically proven to deliver oligonucleotides for RNA editing, such as our product candidates.

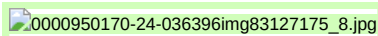
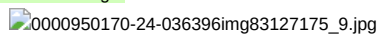


Exhibit 1: Figure 6. Demonstrated greater than 50% editing using GalNAc conjugates in the liver in a preclinical mouse model.

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Our Pipeline Demonstrates the Versatility of the OPERA Platform

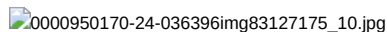
We are advancing a broad pipeline of four programs that are wholly owned and demonstrate the versatility of our OPERA platform. In addition, we have two other wholly-owned programs not reflected in the pipeline chart below: one for an undisclosed target for sAH, and one for a kinase target for cardiometabolic disease. All of our programs are still in the research or preclinical stage of development and their risk of failure is high.



¹ Subject to submission of regulatory filing and authorization to proceed

Exhibit 2: Our proprietary oligonucleotides co-opt endogenous ADAR to perform a single A-to-I base edit on RNA to modify protein function. Delivery of these proprietary oligonucleotides into a cell forms an oligonucleotide-RNA duplex which recruits endogenous ADAR, ultimately editing a target adenosine (A) to inosine (I) on RNA. The location of the edit can lead to a multitude of effects including changes in expression and regulation of mRNA. In the event an edit is made in the coding region of the gene, the mRNA is then translated to a protein with the (I) inosine read as a (G) guanosine, resulting in a modified protein. The resultant therapeutic protein can be applied to go beyond repairing pathogenic SNVs by changing amino acids on proteins implicated in disease biology. Single amino acid changes to non-mutated RNA can create *de novo* modified protein variants with desired altered properties while preserving their broader functional capabilities.

Repairing pathogenic variants: Our OPERA platform enables the development of RNA editing therapies that can repair SNVs on mRNA to express normal proteins through the introduction of precise genetic changes without creating permanent changes to the genome. These normal proteins can be uniquely expressed at desired levels and duration to address both rare and highly prevalent diseases caused by a pathogenic SNV. This approach is especially relevant when the same underlying genetic SNV manifests in a broad disease phenotype from mild to severe forms of the disease.



Leveraging our PCA approach Figure 7. RNA editing of a single nucleotide can restore normal protein expression

Our lead program for future applications AATD addresses a single genetic SNV in the SERPINA1 gene that causes the development of AAT deficiency, which has a high unmet medical need and for which there are no disease modifying treatment options. The disease manifests with a heterogenous population having both liver and lung pathologies. By specifically editing a single nucleotide, the normal synthesis of AAT is restored, resulting in secretion of normal AAT to levels which are predicted to protect the lung from further decline in function. The correction of a subset of AAT produced also prevents aggregation of AAT protein in the liver, thereby potentially alleviating damage to the liver.

Similarly, we are developing a product candidate that addresses a LRRK2 mutation for PD patients. Mutations in LRRK2 that are associated with aberrantly enhanced kinase activity are the most common cause of genetic PD. The G2019S mutation in the LRRK2 protein is the most common pathogenic mutation, accounting for 1–6% of sporadic and 3–19% of familial PD cases. Repairing the G2019S mutated nucleotide can restore the normal LRRK2 protein and return its activity to a physiological state, which we believe may be disease modifying in these patients.

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Other protein modifications

Approximately 85% of the human proteome has historically been considered undruggable through traditional therapeutic modalities as many proteins lack defined small molecule binding sites or are inaccessible by biologics. The versatility of RNA editing, combined with our OPERA platform, addresses a meaningful portion of the undruggable human proteome and broadens the target space. Our target identification and selection for programs is based on strong genetic evidence implicating each target in its disease pathology.

Our initial focus is to make edits to the coding region of a transcriptome. Making changes post-transcriptionally, after the mRNA has been created and prior to the protein being translated, provides an exquisite, selective approach for modifying proteins. In preclinical studies, we have demonstrated that single RNA changes can disrupt protein-protein interactions, prevent protein aggregation, selectively modulate an ion channel and selectively activate a kinase. These modification approaches have the potential to unlock validated target classes that have historically been difficult to drug, enabling us to pursue a broad range of diseases, including those with high prevalence and large market opportunities.



Disrupting Protein-Protein Interaction: Modulating protein-protein interactions provides a novel modality to target intracellular proteins specifically for increasing the activity of the protein. Single amino acid changes to non-mutated RNA can disrupt binding of inhibitors to target proteins, including transcription factors, promoting enhanced biological activity of the target protein. There are two ways this could provide increasing activation, either through a hyperactive protein, or through the presence of a longer half-life or both. Such an approach highlights the broad capabilities of what an RNA editing platform can accomplish in driving biological change.

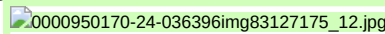


Figure 8. Our oligonucleotides have the ability to disrupt protein-protein interactions using precise edits

One of our programs for disrupting protein-protein interactions is in development for the treatment of severe alcohol-associated hepatitis (sAH). We are selectively modulating a validated transcription factor protein implicated in the disease pathology for sAH. This oligonucleotide product candidate leads to the synthesis of a protein variant that disrupts interaction with its inhibitor and, as a result, increases expression of clinically beneficial downstream target genes. Other approaches have attempted to disrupt the interaction with non-selective small molecules, resulting in unacceptable side effects, or by knocking down the regulatory protein, which is also responsible for regulating other important proteins. In a retrospective analysis of a study looking at sAH patient liver samples, increased expression of these target genes has been shown to have better prognosis. In addition to sAH, this transcription factor is a validated target for other liver, cardiometabolic and inflammatory diseases, which may provide a "pipeline-in-a-product" opportunity.

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Other Target Classes: In addition to disrupting protein-protein interactions, we are also advancing product candidates to prevent protein aggregation, selectively modulate ion channels and activate kinases.

Intracellular protein aggregation is a cause of multiple diseases across the body. Specifically in neurodegenerative diseases, accumulation of specific proteins within neurons are pathogenic including Alzheimer's disease, PD, and ALS. Creating a protein variant that can prevent the aggregation, while preserving its intrinsic function, is a therapeutic approach that has the potential to provide a differentiated therapeutic option over knocking down or silencing the protein through alternate mechanisms.

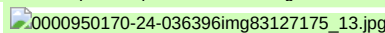


Figure 9. Our product candidates can reduce pathogenic aggregation of undesirable proteins

One of our programs for disrupting protein aggregation is in early-stage discovery for the treatment of ALS. We are selectively modulating TDP-43, an RNA/DNA-binding protein, which carries out a variety of important functions in healthy neurons including initiation of transcription, pre-mRNA splicing, and miRNA processing. In pathological conditions, such as ALS, TDP-43 is depleted from the nucleus and accumulates as protein aggregates in the cytoplasm in hyperphosphorylated, ubiquitinated, and cleaved forms. These aggregates are observed in more than 90% of ALS patients. A single RNA edit to TDP-43 is predicted to lead to the synthesis of a protein variant that does not aggregate and preserves its normal function. Given TDP-43 is essential for neuronal health, knocking down the protein could be detrimental.

We believe that the elegance and versatility of our RNA editing approach will enable a robust pipeline of potentially disease modifying product candidates to treat diseases previously unattainable by genetic medicine approaches. While the above examples demonstrate the breadth of applications enabled by OPERA, we believe our RNA editing approach will bring the first genetic medicine to address the complex genetic underpinnings of highly prevalent diseases.

Our AATD Program: RNA Editing to Repair Pathogenic Missense Variant

Our first development candidate, KRRO-110, is in development as a potential treatment for Alpha-1 Antitrypsin Deficiency, or AATD, that has the potential to be disease-modifying and provide a differentiated therapeutic option. AATD is an inherited genetic disorder that can cause severe progressive lung and liver disease due to a lack of normal alpha-1 antitrypsin protein, or AAT, with varying intensity based on patient genotype and environmental factors. Patients often develop chronic obstructive pulmonary disorder, or COPD, in the lungs and cirrhosis of the liver, which can result in liver failure or death.

There are an estimated 3.4 million individuals with deficiency allele combinations worldwide. There is a single approved modality, a once-a-week infusion of pooled human plasma derived AAT, that does not adequately address the lung or liver manifestations of AATD. Within the United States alone, the opportunity to improve the existing standard of care and expand the treated population represents a large market opportunity.

KRRO-110 is a proprietary RNA editing oligonucleotide that is delivered to liver cells using an established LNP platform to restore production of normal AAT. KRRO-110 is expected to be delivered via intravenous infusion, where it co-opts endogenous ADAR to repair the pathogenic SNV and restore production of normal AAT, creating a clinically differentiated benefit for both liver and lung function in affected individuals.

In addition to the inherent benefits of ADAR-based RNA editing described earlier, we believe our approach has additional potential advantages:

- Provides a disease modifying therapy for both lung and liver manifestations by transiently editing over 50% of RNA transcripts in hepatocytes to restore normal AAT protein
- Provides a treatment option that can be tailored to address the broad spectrum of severity within the AATD population

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- Potential to enable physiologic regulation of AAT using endogenous ADAR, thereby increasing normal AAT production during inflammation
- Fit-for-purpose delivery using a proven LNP to maximize editing efficiency, leading to greater potential clinical benefit

We have generated compelling preclinical data demonstrating proof of concept across multiple RNA editing oligonucleotides targeting the SERPINA1 gene, including KRRO-110. KRRO-110 has achieved targeted durability, high editing efficiency (>50% editing in hepatocytes) and increased expression of normal AAT protein (>70% of total AAT protein in circulation) in an *in vivo* mouse model. We have also shown that earlier generation oligonucleotides that target a different site on the SERPINA1 gene than KRRO-110 have high translation of RNA editing efficiency from mice to non-human primates, or NHPs, demonstrating the potential applicability of our approach in humans. With regard to KRRO-110, we have shown high specificity with no bystander effects in MZ human primary hepatocytes. Additionally, we have demonstrated that intravenous administration at 2mg/kg resulted in secretion of approximately 50uM functional AAT as early as seven days post-single dose in a human transgenic PiZ mouse model. An increase in AAT protein and the inhibition of elastase activity were sustained through week nine when dosed every two weeks, demonstrating durability in mice. Finally, we have shown greater than 40% editing in NHPs utilizing an earlier generation oligonucleotide designed to edit a surrogate SERPINA1 RNA target site.

While we believe we can demonstrate many of the key advantages of RNA editing, we are very early in our development efforts and not yet certain of the results we may achieve. Such uncertainties include, but are not limited to, the level of editing efficiency needed in a target tissue type to achieve a clinical benefit, and associated safety of our edits in humans. Preclinical development of KRRO-110 is ongoing in preparation for a potential regulatory filing in the second half of 2024, and an anticipated interim clinical readout in the second half of 2025. Depending on the evidence of efficacy and tolerability for our candidate in our first clinical study, we plan to pursue expedited regulatory pathways, including potentially requesting Fast Track Designation and Breakthrough Therapy Designation.

AATD Overview

AAT function

AAT is a protease inhibitor belonging to the Serpin family. It is produced in the liver and circulates in its native state in human blood at approximately 1.5 g/L, one of the highest concentrations observed for protease inhibitors. The main role of AAT is to protect tissue from proteases released by neutrophils, such as neutrophil elastase. Neutrophil elastase is an enzyme that fights infections in the lungs but can also attack normal lung tissue. If not sufficiently inhibited by AAT, neutrophil elastase destroys elastin in the lung, leading to degradation of lung function. Factors that increase lung inflammation, such as smoking or infections, increase the elastase burden in the lung, leading to severe and potentially life-threatening lung damage in AATD patients.

Genotypes of AATD

AATD is an inherited, autosomal recessive genetic disorder that is most frequently caused by a single nucleotide variant, or SNV, mutation in the SERPINA1 gene. The most common of these SNVs is the "Z" mutation, corresponding to a mutation of glutamate 342 to lysine, or E342K. A healthy individual typically exhibits an "MM" genotype, or PiMM, while an individual with a single Z allele would exhibit a heterozygous PiMZ, genotype and an individual with two Z alleles would exhibit a homozygous, or PiZZ, genotype.

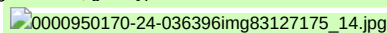


Figure 10. PiMM genotype (normal liver and lung)

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Impact of Z mutations on liver and lung function

The presence of a single Z allele can lead to insufficient production of normal AAT protein, as well as the production of dysfunctional AAT protein, causing manifestations of disease in both the lungs and liver. The severity of disease manifestation can vary according to each patient's genotype, as well as environmental factors, such as exposure to inflammatory respiratory agents or other complications.

PiZZ individuals experience greater manifestations of disease as a result of their very low levels of normal AAT (10%—15% of normal levels), which are insufficient to prevent lung damage post an influx of neutrophils. They are also at high risk of developing emphysema or COPD, which can present in individuals as early as in their thirties and forties. PiZZ individuals with additional environmental risk factors such as smoking or infection frequently develop COPD as early adults and develop very severe symptoms.

In addition to lung disease, PiZZ individuals can also manifest with liver disease as a result of dysfunctional AAT aggregating in the liver. In adults, this can cause liver inflammation and cirrhosis, ultimately leading to liver failure or cancer. In addition, as many as 10% of newborns with the PiZZ genotype develop cholestatic hepatitis. A quarter of impacted neonates suffer acute liver failure and require an emergency transplant.

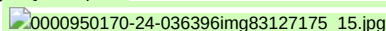


Figure 11. PiZZ genotype that results in fibrotic liver and decreased lung function

Data from the UK Biobank, or UKBB, as well as published literature, have allowed researchers to determine the threshold levels of circulating AAT that are directly linked to the PiMZ and PiZZ genotypes. In Figure 12 below, the range of AAT levels associated with normal individuals (PiMM) is compared with the range of AAT levels observed in mutated PiMZ and PiZZ patients.

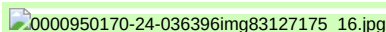


Figure 12. Median Levels of AAT and link to outcomes in liver and lung

In Figure 13 below, the Odds Ratios, or OR, associated with developing COPD and cirrhosis of the liver are compared across the two genotypes, with key findings summarized below:

- **COPD:** PiMZ individuals have minimal increased risk of developing COPD relative to healthy PiMM individuals, while PiZZ individuals are at very high risk with an OR of 8.8
- **Cirrhosis of the liver:** PiMZ individuals have mildly elevated risk of developing cirrhosis of the liver with an OR of 1.5, while PiZZ individuals have significantly elevated risk with an OR of 7.8

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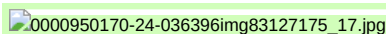


Figure 13. Risk of developing COPD and cirrhosis for different genotypes associated with AATD. Adapted from "The undiagnosed disease burden associated with alpha-1 antitrypsin deficiency genotypes." By Nakanishi T, Forgetta V, Handa T, et al. Eur Respir J 2020; 56:2001441

Based on these findings, we believe that achieving normal AAT protein levels between the ranges of the PiMZ and PiMM genotypes has the potential to alleviate the increased risk of COPD and cirrhosis of the liver, and to meaningfully improve clinical outcomes for PiZZ patients. We further believe that by achieving >50% editing efficiency across cells, we can reach these target levels and modify disease progression.

Prevalence of AATD and limitations of currently approved therapy

AATD is one of the three most common, potentially lethal, rare diseases affecting those of European descent. Worldwide, there are an estimated 3.4 million individuals with deficiency allele combinations. Studies suggest that clinical unawareness of AATD results in a significant number of patients that go undiagnosed or misdiagnosed. There are currently an estimated 100,000 patients in the United States with a PiZZ genotype, and 125,000 patients across the United Kingdom, Germany, France, Spain and Italy. Studies of PiMZ prevalence suggest as many as one in 49 individuals in the United States and one in 58 individuals across Europe.

The only FDA-approved treatment for patients with lung manifestations of AATD (co-indicated with COPD) is augmentation therapy, which utilizes AAT protein purified from pooled human plasma. The purified AAT is administered weekly by intravenous infusion with the goal of maintaining a serum level of AAT above the 11 μ M threshold. Even when the serum level can be maintained at or above this threshold, augmentation therapy has not clearly demonstrated its ability to adequately address lung damage nor liver inflammation caused by AAT aggregation. Augmentation therapy is approved in only a few countries due to its limited efficacy. Lung and/or liver transplantation are the only other available treatment options, outside of standard management of the disease manifestations of AATD.

Despite being minimally effective and not fully addressing the needs of many AATD patients, augmentation therapy currently represents approximately \$1.4 billion in annual sales worldwide. KRRO-110 has the potential to elevate the standard of care and expand the number of patients on treatment and potential to be a leader with a large market opportunity worldwide.

Limitations of Alternative Treatments in Development for AATD

There are a number of therapies in development to treat AATD. Certain DNA editing approaches attempt to add a normal copy of SERPINA1 gene or permanently correct the mutation within the SERPINA1 gene. DNA editing as a treatment would likely be evaluated on a risk-benefit trade-off relative to the severity of the manifestation of AATD, limiting

the applicability of DNA editing approaches to the broader AATD patient population.

Additional approaches outside of DNA editing are also in development. There are approaches which attempt to use siRNA to knock-out the production of dysfunctional AAT protein, which only alleviates the liver manifestation of AATD, while potentially worsening the lung manifestation. Replacing plasma derived protein for augmentation therapy with a fusion protein is another approach in development. This fusion protein aims to introduce AAT on an antibody scaffold to improve upon the existing dosing paradigm and activity levels achieved in augmentation therapy. Fusion proteins do not resolve the liver manifestation and are unable to physiologically regulate AAT levels. Lastly, small molecule correctors attempt to promote proper folding of the Z-AAT protein. To date, small molecule correctors have been unable to achieve normal AAT levels and clinical development is focused only on the liver manifestation of AATD.

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We believe many of these approaches have inherent limitations including the following:

- Inability to adequately address the spectrum of clinical pathologies associated with AATD
- Inability to achieve adequate expression of normal AAT to bring patients back to PiMM genotype
- Considerable safety and tolerability concerns
- Potential issues around manufacturability and scalability for the AATD population

Our Approach to Overcome the Limitations: Transiently Correcting the SERPINA1 Variant on RNA

We are developing KRRO-110 to treat patients with AATD. KRRO-110 is designed to leverage endogenous ADAR to make a single base edit in SERPINA1 mRNA, correcting the amino acid codon created by the pathogenic E342K SNV which stems from a single G-to-A mutation. Specifically, KRRO-110 edits the adenosine (A) to an inosine (I), thereby correcting the faulty amino acid and leading to the production of normal AAT protein.

Our goal is to bring individuals with the Z mutation to a phenotype where over 50% of RNA has been corrected to produce normal AAT protein. This would result in levels of AAT consistent with individuals in the upper half of the PiMZ genotype and the fully healthy PiMM genotype. Through human transgenic mouse models, we have shown our ability to drive the required change in RNA sequence with high efficiency, leading to secretion of AAT at target levels.

We believe our approach has multiple potential advantages, in addition to those conferred by the RNA editing modality:

- **Provides a tailored disease modifying treatment option to address the heterogeneity of the AATD population:** We leverage a transient base editing approach leading to restoration of normal AAT. The transient nature of our approach allows us to address a broader AATD patient population, inclusive of PiMZ and PiZZ genotypes. As transient editing is not permanent in nature, we have the ability to adjust dosing and even cease dosing as needed, providing a meaningful benefit in potential safety profile.
- **Provides a disease modifying therapy for both lung and liver manifestations:** By transiently editing over 50% of RNA transcripts in hepatocytes, we believe we can restore levels of normal AAT protein consistent with a PiMZ to PiMM phenotype. These levels of normal AAT have the potential to prevent further lung damage and reduce the risk of dysfunctional AAT aggregating in the liver.
- **Potential to enable physiologic regulation of AAT using endogenous ADAR:** Augmentation therapy and other treatments targeting static thresholds for AAT expression do not address the underlying mechanism of AAT regulation, which is endogenously regulated by inflammation and can sometimes lead to as much as 90uM of AAT in humans. During an inflammatory response, there is a simultaneous increase in ADAR levels. Our ADAR-based therapy has the potential to restore natural physiologic regulation by increasing the prevalence of editing during periods of greater AAT production.
- **Uniform distribution of drug to liver cells to maximize editing:** Unlike other modalities that focus on DNA editing, our product candidates, including KRRO-110, have demonstrated a uniform distribution within the liver, including in NHPs. We believe this will allow our therapy to restore production of normal AAT protein in every cell, reducing reliance on the chance of a survival benefit for edited cells as in DNA editing.
- **Efficient delivery using a proven LNP:** AAT is the fifth most abundant protein in circulation, with a large number of transcripts that require editing to achieve expression of normal protein. LNPs provide a significant benefit to delivery of RNA-editing oligonucleotides by increasing the likelihood of sufficient distribution into liver cells. In March 2023, we entered into an agreement with Genevant Sciences GmbH, or Genevant, a well established leader in the LNP space, to provide access to clinically validated LNP technology to optimize delivery of KRRO-110. Preclinical studies of this LNP delivery technology have shown improved dose-dependent efficacy with reduced clinical chemistry and adverse events. We are pursuing development of KRRO-110 with an optimized LNP from Genevant (GVT-1) for delivery.

KRRO-110

Summary of our preclinical studies and data generated to date leading to KRRO-110 nomination

We have generated highly compelling preclinical data that forms the basis for our proof of mechanism. We have affirmed that multiple disease modifying early generation product candidates have demonstrated proof-of-concept in *in vivo* studies leading to the nomination of KRRO-110 as a development candidate.

Earlier generation product candidates have independently achieved clinically meaningful expression of normal AAT protein consistent with a PiMZ genotype within preclinical *in vivo* animal models while using clinically relevant doses administered on a weekly or biweekly basis. Given that human protein half-life is much longer than other species, we believe our therapies will support a longer dose interval in the clinic. We have initiated preclinical dose-limiting toxicity safety studies and nominated our first development candidate, KRRO-110, in December 2023.

***In vitro* activity in human cells:** Our initial design iterations for RNA-editing oligonucleotides were conducted in *in vitro* human systems, specifically containing human ADAR and human SERPINA1 genes with a Z allele. By leveraging the capabilities of our OPERA platform, we have generated multiple product candidates that achieved increased editing activity in human *in vitro* systems.

In Figure 14 below, we were able to demonstrate greater than 50% editing efficiency at the E342K mutation within stem cell derived hepatocyte like cells, or HLCs, with KRRO-110. HLCs harbor both alleles, an important quality that has the potential to be predictive of function *in vivo*. We also demonstrated editing in MZ primary human hepatocytes, or PHH, which harbor a single Z allele.



- 1 HLCs derived from ZZ patient, transfected with RNAiMAX with 1U/uL of IFN, editing measured 48-hours post transfection via amplicon-seq
- 2 Primary hepatocytes from MZ donor, free-uptake of LNP, editing measured 48-hours post uptake via amplicon-seq

Figure 14. KRRO-110 demonstrated >50% editing in *in vitro* systems with the Z genotype



Figure 15. Negligible *in vitro* cis off-target editing observed for KRRO-110 in MZ hepatocytes

KRRO-110 demonstrates high selectivity for editing at the E342K RNA site, as shown in Figure 15. No off-target editing was observed in MZ primary human hepatocytes assessed at 100 base sites above and below the E342K site, against background levels. A concentration gradient is observed with a dose-response at the E342K edit site.

Preclinical *in vivo* activity in mice with KRRO-110: To assess and differentiate our development candidate, KRRO-110, in a mouse model used widely in the AATD field, we used a human transgenic NSG-PiZ mouse. The NSG-PiZ transgenic mouse expresses the human SERPINA1 gene with the Z-mutation. As detailed in Figures 16 and 17 below, intravenous administration of KRRO-110 at 2 mg/kg resulted in >50% editing and secretion of approximately 50µM AAT as early as seven days post-single dose in the NSG-PiZ mouse model. Increase in AAT protein and the inhibition of elastase activity were sustained through week nine when dosed every two weeks, demonstrating durability in mice.

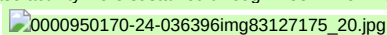


Figure 16. Achieved >50% editing in human transgenic mouse model of Z genotype with a single dose



Figure 17. Secretion of functional AAT (approximately 50uM) as early as 7 days post-single dose

Preclinical *in vivo* activity in mice with earlier generation oligonucleotides: Our screening preclinical pharmacology studies have been conducted using a second C57BL/6-PiZ mouse model and licensed by us from Dr. Jeff Teckman's laboratory at St. Louis University School of Medicine. Dr. Teckman is the preeminent expert on the study of AATD. The C57BL/6-PiZ transgenic mouse model also expresses the human SERPINA1 gene containing the Z mutation.

As part of our preclinical studies, we have evaluated multiple oligonucleotides in varying doses in PiZ mice. KB-0794, an earlier generation oligonucleotide, demonstrated editing efficiency as high as 63% on day four following the administration of a single 3mg/kg dose. Normal M-AAT protein was observed at an 18 µM concentration on day four, demonstrating the potential relationship between editing efficiency and secretion of normal AAT. Upon observing the high editing efficiency of KB-0794, we proceeded to conduct an additional preclinical *in vivo* study where four groups of mice were given a lower dose of 2mg/kg and observed in a multi-dose study that lasted up to four weeks. Key takeaways from the multi-dose study included the following:

- Achieved up to 54% editing efficiency with up to 20uM of normal AAT, constituting 72% of total protein in circulation
- Liver polymers associated with the dysfunctional AAT protein were reduced at day 28, pointing to a potential to provide liver benefit through clearing of aggregates

The half-life of AAT in mice and NHPs has been observed to be around 1-2 days and 2-4 days, respectively. Human AAT has a longer half-life of 4-6 days, and when coupled with the optimization of our oligonucleotide drug product and the accumulation of drug product observed in the multi-dose preclinical studies, we believe that we will be able to achieve greater durability and a longer dosing interval in the clinic than the current once weekly or biweekly interval conducted in our preclinical studies.

Our preclinical screening studies to identify product candidates were originally conducted using an LNP delivery vehicle comprising lipids used in the approved product ONPATTRO®. Over the past decade, the field of LNP delivery has made advancements as measured by safety profile and tolerability. Our product candidates, when combined with current generation LNP delivery technology from Genevant, have demonstrated optimized editing efficiency, safety and tolerability.

In a preclinical study to compare the editing efficiency of a previous generation LNP (the comparator LNP) and current generation Genevant LNPs (GVT-1 and GVT-2), we evaluated C57BL/6-PiZ mice after receiving a single 2mg/kg dose of KB-0794 via each of the three delivery vehicles. As detailed below in Figure 18, GVT-1 and GVT-2 achieved comparable or higher editing of 37% and 65%, respectively, as compared to 29% editing for the comparator LNP. Post a single LNP dose, the percentage of normal-AAT increased to 66% for GVT-1 and 85% for GVT-2, compared to 56% for the comparator LNP, showing potential for disease-modifying effects.

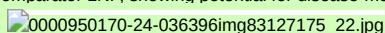


Figure 18. Comparison of editing efficiency and circulating normal protein in C57BL/6-PiZ mice between MC3 LNP and current generation Genevant LNPs (GVT-1 and GVT-2)

Nomination of KRRO-110

The above data demonstrates the highly compelling preclinical data that forms the basis for our proof of mechanism and therapeutic approach. Additionally, we have generated non-GLP toxicology data and affirmed that multiple disease modifying early generation product candidates have demonstrated proof-of-concept in in vivo studies. The complete data set has led to the nomination of KRRO-110 as a development candidate.

Translation to NHPs

In addition to our MS Program, preclinical in vivo studies conducted using the PiZ mouse models described above, we have also generated a translational model to validate the potential for delivery and ability to edit the SERPINA1 gene in NHPs with an

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earlier generation oligonucleotide. Because the human SERPINA1 gene in NHPs does not harbor the E342K mutation, we are demonstrating our oligonucleotide's ability to edit within the coding region of the SERPINA1 gene and the ability to translate that preclinical in vivo editing from the PiZ mouse model to NHPs.

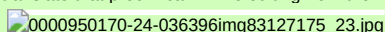


Figure 19. Editing de novo adenosine on cyno SERPINA1 to elucidate editing in higher species

We evaluated the potential editing efficiency of GVT-1 and GVT-2 for the SERPINA1 coding region in NHPs. As detailed in Figure 20 below, the observed editing rate of GVT-2 was meaningfully higher at 34%, relative to 13% in the historical MC3 study. ALT levels, a measure of safety and tolerability, were meaningfully lower in GVT-1 and on par between GVT-2 and the LNP comparator. These results show that our product candidates, when combined with current generation Genevant LNPs, can demonstrate a desirable safety profile while increasing the editing efficiency.



Figure 20. Comparison of editing translation in NHPs between MC3 LNP and current generation Genevant LNPs (GVT-1 and GVT-2)

Optimization of our NHP surrogate led to KB-1494 formulated in the current generation Genevant LNP (GVT-1). Upon receiving a 2mg/kg intravenous dose, liver editing was measured 4-5 days and 14-15 days after the initial dose, in mice and NHPs, respectively. As detailed in Figure 21, the observed editing rate of GVT-1 in NHPs was meaningfully higher at greater than 40%, relative to 26% observed in mice, and sustained for approximately two weeks. These results further illustrate the translation of RNA editing across mouse and NHP preclinical species.

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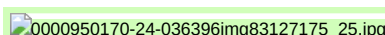


Figure 21. Editing of SERPINA1 coding region in NHPs and C57BL/6-PiZ model showed correlation

Next Steps

Preclinical development of KRRO-110 is ongoing in preparation for a potential regulatory filing in the second half of 2024 to enable the initiation of human clinical studies, with an anticipated interim clinical readout in the second half of 2025.

Our Parkinson's Disease Program: Repairing Pathogenic Variants

We are developing proprietary oligonucleotides that address the leucine-rich repeat kinase 2, or LRRK2, mutation for Parkinson's Disease, or PD, patients. This is the second program that leverages our ability to generate product candidates to repair pathogenic variants, similar to the AATD program.

Parkinson's Disease:

PD is a complex, multifactorial progressive disease that is caused, in part, by the loss of dopaminergic neurons in a structure of the brain called the substantia nigra, which is essential for the proper control of the body's movement. Approximately 10% of PD cases are attributed to inherited genetic mutations, while the remaining cases are considered idiopathic or sporadic. Mutations in *LRRK2* are the most common genetic cause of PD and increasing evidence also provides support for a role of LRRK2 in idiopathic PD. PD is the second most common neurodegenerative disease with approximately 1.0 million people in the United States diagnosed. Despite the large commercial market opportunity, there remains significant unmet need as there is no cure, and current available therapies only relieve the symptoms of PD.

LRRK2 is linked to several cellular processes including mitochondrial function, endocytosis, vesicle trafficking, and the lysosomal autophagy pathway. Additionally, LRRK2 is implicated in regulating cytokine levels and neuroinflammation. There are various mutations in LRRK2 that can result in PD, the most common of which is the pathogenic G2019S mutation that accounts for 1-6% of sporadic and 3-19% of familial PD cases.

Our Differentiated Approach and Results

Our approach is to make a single base edit to repair the protein caused by the G2019S mutation in LRRK2, which is expected to result in returning activity to the normal physiological state. We believe this change may result in disease modification.

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As shown in Figure 22 below, our PCA preliminary screening process in heterozygous LRRK2 G2019S patient-derived fibroblasts identified several product candidates that achieved >80% editing in *LRRK2* compared to only 47% in controls. The 47% represents half the transcripts having the mutation at baseline.

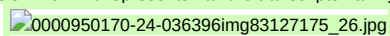


Figure 22. Editing of the G2019S mutation LRRK2 using our product candidates (100 nM)

Next Steps

We are currently screening additional oligonucleotide designs and optimizing *in vitro* assays to correlate LRRK2 editing with downstream functional endpoints. Additionally, we plan to evaluate our product candidates in a LRRK2 G2019S humanized mouse model.

Our Severe Alcohol-Associated Hepatitis Program: Disrupting Protein-Protein Interactions

Another of our programs is focused on the treatment of severe alcohol-associated hepatitis, or SAH, and demonstrates the versatility of our platform to modulate proteins. This program leverages our RNA editing technology to modulate the activity of a naturally occurring protein by disrupting protein-protein interactions. We are selectively modulating a protein transcription factor implicated in the disease pathophysiology for SAH. We believe that this approach enables the synthesis of a protein variant that disrupts interaction with our inhibitor and as a result, will be free to express downstream target genes. SAH patients with higher levels of expression of these downstream target genes have been shown to have better prognosis in a prior study examining liver biopsies at the time of diagnosis.

Severe Alcohol-Associated Hepatitis

The burden of alcohol use and alcohol use disorders contributes significantly to the health care costs for alcohol-related diseases. These patients incur direct costs to the health care system for medical care, and indirect costs to society due to a loss of workforce productivity, absenteeism, injury, early retirement and mortality. Alcohol overconsumption can lead to the development of liver damage that can manifest as fatty liver disease, alcohol-associated hepatitis and cirrhosis. The amount of alcohol intake that puts an individual at risk for alcohol-associated hepatitis is not known, but most patients have a history of heavy alcohol use for two or more decades. It is estimated that two million people die of liver disease each year, and up to half of these cases are due in part to alcohol overconsumption. There are around 300,000 hospitalizations per year for SAH in the United States. SAH is an acute condition with a mortality rate of 25%–45% within 90 days of hospitalization.

There are no FDA-approved treatments for SAH. Prednisolone is used off-label in this setting and is the only treatment available. However, many patients fail to respond to prednisolone or are contraindicated, and studies have failed to show survival benefit at 90 days. Physicians may also prescribe pentoxifylline, an anti-inflammatory, or N-acetylcysteine, an antioxidant, but the benefit of these drugs for SAH is not well established. Additionally, some SAH patients may be candidates for a liver transplant. It has been

documented that survival for sAH patients is mainly driven by liver injury and not significantly impacted by alcohol-relapse. Current strategies to address harmful alcohol use and the development of pharmacotherapies remain largely ineffective, leading to substantial unmet need for advancement of policy efforts and development of novel therapies with effective mechanisms of action.

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Our Differentiated Approach and Results

We are developing a product candidate that increases expression of a transcription factor (TFX) implicated in sAH. By selectively modifying a single amino acid, we are able to disrupt interactions between the target protein and our inhibitor, as depicted in Figure 23 below.

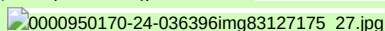
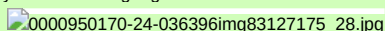


Figure 23. Changing a single amino acid disrupts binding of a transcription factor to its inhibitor

We have generated preclinical data for our sAH product candidates, demonstrating target editing and activation of target transcription factor activity in both preclinical *in vitro* and *in vivo* studies. *In vitro*, our oligonucleotides dose-dependently edited the target gene mRNA in human liver cells reaching > 70% editing efficiency as shown in Figure 24 below.

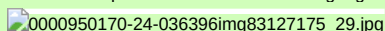


¹Hep3B cells transfected with RNAiMAX at the indicated concentrations with two targeting oligos, editing measured 48-hours post transfection via amplicon-seq

Figure 24. Our product candidate edits transcription factor RNA at the validated target site in a dose-responsive manner

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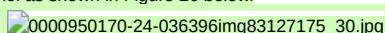
In vivo, our product candidates edited the target mRNA and induced expression of downstream target genes by up to 7x in mouse liver tissue as shown in Figure 25 below.



²Wild type mice dosed with LNP-targeting oligos at a concentration of 3 mg/kg, gene expression measured via quantitative PCR from liver harvested 1 day post dose

Figure 25. Hyperactive variant of transcription factor increased expression of downstream gene up to 7x *in vivo*

The product candidate has also demonstrated activity in an *in vitro* model of sAH, showing protection against cytotoxicity induced by alcohol and TNF-alpha in human liver cells overexpressing CYP2E1, the enzyme that metabolizes alcohol as shown in Figure 26 below.



³Hep3B-CYP2E1 cells transfected with RNAiMAX at the indicated concentrations with two targeting oligos, cell viability measured 48-hours post transfection via CellTiter-Fluor Cell Viability Assay from Promega

Figure 26. RNA editing demonstrates increased viability of liver cells in an *in vitro* model of sAH

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Additionally, as seen in Figure 27 below, the product candidate demonstrated activation of a transcription factor by creating a de novo protein variant resulting in sustained downstream activity in NHPs lasting longer than 21 days, demonstrating potential to preserve transcription factor function, and increase durability of its related protein variant.



Figure 27. Sustained downstream activity in NHPs lasting longer than 21 days

Next Steps

We are currently evaluating additional oligonucleotide designs and conducting preclinical studies to confirm that our product candidates will ameliorate disease phenotype in models of alcohol-induced hepatitis. We also plan to evaluate our approach in NHP studies.

Our Amyotrophic Lateral Sclerosis Program: Disrupting Protein Aggregation

We are developing proprietary oligonucleotides targeting the mRNA for TAR DNA binding protein 43, or TDP-43, a protein associated with the etiology of amyotrophic lateral sclerosis, or ALS.

Amyotrophic Lateral Sclerosis

ALS is an adult-onset, progressive, and fatal neurodegenerative disorder that causes muscle weakness, paralysis, and ultimately death. The majority of ALS patients die from respiratory failure within three to five years after symptom appearance, with a small percentage of patients surviving beyond 10 years. Despite being classified as a rare disease by the FDA and the EMA, ALS is considered one of the more common neurodegenerative diseases worldwide. Prevalence estimates vary, but it is widely accepted that there are at least an estimated 25,000 ALS patients in the United States. There is currently no cure for ALS, and currently approved therapies either only provide symptomatic relief or slow the overall progression of the disease.

Our Differentiated Approach and Results

Our approach is to selectively modulate TDP-43, an RNA/DNA-binding protein, which carries out a variety of important functions in healthy neurons, including initiation of transcription, pre-mRNA splicing and miRNA processing. Hyper-phosphorylated and ubiquitinated TDP-43 deposits form inclusion bodies in the brain and spinal cord of patients with ALS and frontotemporal dementia, or FTD. The majority of ALS and FTD cases are sporadic, and more than 90% and 45% of ALS and FTD patients, respectively, have TDP-43 aggregations in neurons. Less than 10% of ALS cases are familial, and mutations in *TARDBP*, the gene encoding TDP-43, are responsible for approximately 4% of familial ALS. Given the importance of TDP-43's role in maintaining healthy neurons, the generation of a protein variant with the desired non-aggregating property could potentially have therapeutic benefit for the majority of ALS and FTD patients. We believe that by leveraging the ability of RNA editing to affect a single base edit in *TARDBP*, we can lead to the synthesis of a TDP-43 protein variant that does not aggregate, thereby restoring our normal function.

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We have created a series of TDP-43 variants that contain single amino acid changes designed to alter post-translational modification by phosphorylation, ubiquitination, acetylation or cleavage with the intent of reducing the ability to aggregate while maintaining function in RNA metabolism. We believe that modulating TDP-43 through the introduction of specific amino acid changes into TDP-43 mRNA sequence is preferable to other approaches that try to address protein aggregates after they form, to non-specifically prevent stress granule formation, or to target a single TDP-43 downstream target. We have engineered mutations amenable to an RNA edit using our OPERA platform that limit the formation of TDP-43 inclusion bodies *in vitro*. Additionally, we have demonstrated meaningful editing of TDP-43 targets sites with our product candidates in a human neuroblastoma-derived cell line (SK-N-AS) as demonstrated in Figure 28 below.

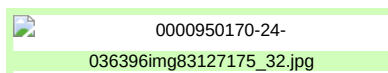


Figure 28. Editing of TDP-43 mRNA using our product candidates (100 nM)

We intend to initially pursue ALS with this approach and has the opportunity to expand our pipeline to other neurodegenerative diseases, such as FTD.

Next Steps

We are continuing to design and screen additional oligonucleotides in SK-N-AS cells to identify proprietary oligonucleotides for further evaluation in aggregation assays. Furthermore, we are identifying and characterizing ALS cell lines including genetic-induced models and patient cell lines, to test the efficacy of TDP-43 protein variants in disease models.

Our Pain Program: Selective Modulation of Ion Channels

We are developing proprietary oligonucleotides that selectively modulate ion channels associated with pain.

Overview of Pain Indications

Pain is a condition that millions of patients experience and is often a component of rare and highly prevalent diseases. Pain can be generally classified as either acute or chronic and can be further segmented into subcategories including nociceptive or neuropathic pain. There are several classes of therapeutics to target the numerous pathways that cause pain, including opioids, nerve growth factors and ion channel blockers. Many of these treatment methods involve non-specific targeting of pathways that lead to off-target effects. Despite a large commercial market opportunity, there remains significant unmet needs for safe and effective pain management, including non-opioid therapeutics.

Several classes of drugs, including local anesthetics, such as lidocaine, are ion channel blockers, although they do not show a high degree of specificity and thus inhibit many types of sodium channels rather than selectively blocking $Na_v1.7$. No highly selective small molecule product candidates have been FDA-approved as therapeutics. One of

the challenges in developing a small molecule inhibitor of Na_v1.7 is the high degree of homology with other voltage gated sodium channels, inhibition of which has been linked to safety concerns.

Our Differentiated Approach and Results

The introduction of genetic changes into the mRNA encoding Na_v1.7 demonstrates the potential of RNA editing to create highly differentiated and selective therapeutics for ion channels. Na_v1.7 is a voltage-gated sodium channel that plays a critical

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role in the generation and conduction of action potentials and is thus important for electrical signaling in the nervous system. Na_v1.7 is highly expressed in the pain sensing dorsal root ganglion neuron. Genetic inactivation of SCN9A, the gene encoding Na_v1.7, in mice results in the inability to sense pain from inflammatory stimuli. In humans, mutations that lead to inactivation of Na_v1.7 function result in a genetic condition known as Channelopathy-associated insensitivity to pain, or CIP. Individuals with CIP have severely diminished ability to sense pain. By contrast, mutations that activate Na_v1.7 result in intense pain.

Through our RNA editing technology, we have generated a series of site-specific changes in Na_v1.7 that modulate our ion channel function such that it mimics a small molecule sodium channel blocker. We believe that using RNA editing to introduce these changes in patients has the potential to address a wide range of clinical applications. In directing our internal research, research collaborations, and in-licensing efforts, we intend to target areas of high unmet medical need for which deliver potent analgesic activity without the underlying disease process involves loss or degeneration of key cells dose-limiting toxicities that could be reversed using PCA. We believe the PCA approach could further be applied to diseases of the muscle, gastrointestinal tract, skin, and bone. We intend to continue to identify areas with high unmet need where our PCA approach and novel approach to regenerative medicine could lead to potentially disease-modifying therapeutics that create healthy functional tissues and improve peoples' lives. have been observed by other sodium channel blockers.

8 We have demonstrated that rationally designed single amino acid changes to unique target sites are sufficient to decrease the activity of Na

v1.7. Electrophysiology studies performed in CHO cells transfected with plasmids expressing channel variants demonstrated biophysical properties that are associated with a decrease in Na_v1.7 channel activity compared to fully functional Na_v1.7. Additionally, we have demonstrated meaningful editing for these target sites in SK-N-AS cells as shown in Figure 29 below.



Manufacturing Figure 29. Editing of Na_v1.7 using our product candidates (100nM)

Next Steps

We are optimizing and screening our proprietary oligonucleotides in electrophysiology assays. Furthermore, we will perform a high throughput screen of Na_v1.7 variants to identify potential novel ion channel variants with enhanced crippling of electrophysiology activity.

Our Cardiometabolic Disease Program: Activating Kinases

We are developing proprietary oligonucleotides that activate a kinase involved in cardiometabolic disease. Cardiometabolic disease encompasses a broad range of complex, multifactorial diseases including cardiovascular disease, diabetes, chronic renal failure and obesity, among others. A number of validated cardiometabolic disease targets such as kinases have been identified but have historically been difficult to drug.

We have generated a site-specific change in a validated kinase that is a central regulator of energy homeostasis. In an *in vitro* mutagenesis study, a site-specific change led to activation of the kinase and an increase in the phosphorylation of its downstream target. We believe that using RNA editing to introduce these changes with an oligonucleotide in patients has the potential to deliver efficacy that has been unattainable when using other modalities.

Pioneering RNA Editing to Deliver the Future of Medicine

Each of our programs demonstrate the versatility of the ADAR-mediated RNA editing approach. Importantly, we are able to not only address classes of diseases caused by deleterious effects of misfolded or misdirected proteins, but we can also potentially utilize genetics to identify highly prevalent diseases where therapeutic benefit can be generated through alteration of

Our product candidates consist of small chemical compounds to stimulate cell and tissue regeneration *in vivo*. As a result, we can rely on the well-established and available

manufacturing and drug-delivery technologies developed over decades by the pharmaceutical industry. We source our active pharmaceutical ingredients from contract manufacturers with a track record of FDA-compliant GMP manufacturing. After rigorous internal and external quality control testing, we release these materials to additional contract manufacturers for formulation and packaging into final drug product for use in clinical testing. We expect to use a similar hybrid of internal and contract resources for commercialization of our products, at least until our operations reach a scale sufficient to justify investment in internal manufacturing capacity.²⁸

Intellectual property protein function or expression. We will continue to selectively identify and pursue additional targets and indications based on a range of technical, clinical, and commercial factors to build a robust and differentiated pipeline. However, RNA editing is a novel technology that is not yet clinically validated for human therapeutic use. The approaches we take to discover and develop novel therapeutics are unproven and may never lead to marketable products. We are not aware of any clinical trials for safety or efficacy having been completed by any third party using RNA editing and nor are we aware of any RNA editing therapeutic product that has been approved in the United States or Europe. It will be many years before we commercialize a product candidate, if ever.

Manufacturing and Supply Arrangements

We **strive** currently have no commercial manufacturing capabilities. For our initial wave of clinical programs, we intend to **protect** use qualified third-party CMOs with relevant manufacturing experience in genetic medicines. we plan to partner with suppliers and **enhance** CMOs to produce or process critical raw materials, bulk compounds, formulated compounds, viral vectors or engineered cells for IND-supporting activities and early-stage clinical trials. At the **proprietary** appropriate time in the product development process, we will determine whether to establish in-house GMP manufacturing capabilities for some core technologies or continue to rely on third parties to manufacture commercial quantities for any products that we may successfully develop.

We also in license technology inventions, for our fit-for-purpose delivery systems, including LNP delivery systems. For example, in March 2023, we entered into a collaboration and **improvements that are commercially important** license agreement with Genevant, a well established leader in the LNP space, to provide access to clinically validated LNP technology to optimize delivery of our AATD product candidate, KRRO-110. Preclinical studies of this LNP delivery technology have shown improved dose-dependent efficacy with reduced clinical chemistry and adverse events. For additional information relating to the **development** financial terms of such agreement, see Note 13 to our **business**, including by seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties. We also **rely** audited consolidated financial statements included elsewhere in this Annual Report on trade secrets, confidential information and know-how, continuing technological innovation, and in-licensing opportunities to develop, strengthen, and maintain our proprietary position in our field. Form 10-K.

Our future commercial success depends, in part, on our ability to: obtain and maintain patent and other proprietary protection for commercially important technology, inventions, and know-how related to our business; defend and enforce our intellectual property rights, in particular our patent rights; preserve the confidentiality of our trade secrets; and operate without infringing, misappropriating, or violating the valid and enforceable patents and proprietary rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell, or importing products identical or similar to ours may depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

Competition

The **patent positions of pharmaceutical and biotechnology industries, including the gene therapy and pharmaceutical companies like ours gene editing fields**, are generally **uncertain** characterized by rapidly advancing technologies, intense competition, and can involve complex legal, scientific, and factual issues. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. We also cannot ensure that patents will issue with respect to any patent applications that we or our licensors may file in the future, nor can we ensure that any of our owned or licensed patents or future patents will be commercially useful in protecting our product candidates and methods of manufacturing the same. In addition, the coverage claimed in a patent application may be significantly reduced before a patent is issued, and its scope can be reinterpreted and even challenged after issuance. As a result, we cannot guarantee that any of our products will be protected or remain protectable by enforceable patents. Moreover, any patents that we hold may be challenged, circumvented, or invalidated by third parties. See "Risk factors—Risks related to our intellectual property" for a more comprehensive description of risks related to our **strong emphasis on intellectual property**.

In an effort to secure our intellectual property positions we generally file patent applications directed to our programs. As of February 1, 2023, we owned, licensed, or have an option to license 34 patent families. These patent families include 31 U.S. patents, 128 ex-U.S. patents, 23 pending U.S. utility patent applications, 110 pending ex-U.S. utility applications, and 1 PCT patent application.

The intellectual property portfolio as of February 1, 2023 is summarized below. Prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the U.S. Patent and Trademark Office may be significantly narrowed before issuance, if issued at all. We expect this may be the case with respect to some of our pending patent applications referred to below.

Multiple sclerosis program

We own intellectual property directed to the treatment of MS and we advise on an exclusively in-licensed portfolio of intellectual property directed to the treatment of MS from The Scripps Research Institute. As of February 1, 2023, no development candidate has been designated, but the intellectual property portfolio for our MS research program currently includes 3 patent families including 4 U.S. patents, 15 ex-U.S. patents, 1 pending U.S. utility patent application, 10 ex-U.S. patent applications, and 1 PCT patent

application. While we believe that the specific our differentiated technology, scientific expertise, and generic claims, contained in our U.S. and ex-U.S. patents provide protection for the claimed pharmaceutical compositions and methods of use third parties may nevertheless challenge such claims. If any such claims are invalidated or rendered unenforceable for any reason, we will lose valuable intellectual property rights, position provide us with competitive advantages, we face potential competition from a variety of companies in these fields. There are several companies using synthetic oligonucleotide or base editing technology, including Beam Therapeutics, Verve Therapeutics, Prime Medicine, ProQR, and our ability to prevent others Wave Life Sciences. Several additional companies utilize other editing technologies, including Edigene and Shape Therapeutics. In addition, we face competition from competing companies utilizing gene therapy, oligonucleotides, and DNA editing technologies such as base and prime editing.

Any product candidates that we successfully develop and commercialize will compete with us would be impaired. Any U.S. or ex-U.S. patents existing therapies and new therapies that may issue from pending applications become available in the future that are approved to treat the same diseases for which we own or exclusively in-licensed, if any, may obtain approval for our MS program are projected to have a statutory expiration date between 2032 and 2042, excluding any additional term for patent term adjustments or patent term extensions. The term product candidates. This may include other types of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application.

Hearing loss

The patent portfolio for hearing loss is based upon our owned and in-licensed patent families that include patents and patent applications directed generally to compositions of matter, pharmaceutical compositions, and methods of using the same to treat hearing loss; and specifically directed to compositions of matter of FX-322, pharmaceutical compositions of FX-322 and methods of using the same to treat hearing loss. The in-licensed patents and patent applications are subject to license agreements with Massachusetts Institute of Technology and Massachusetts Eye and Ear described herein. As of February 1, 2023, we have rights to, through ownership and in-licensing, 30 patent families, including 27 U.S. patents, 112 ex-U.S. patents, 22 pending U.S. utility patent applications, and 93 pending ex-U.S. patent applications related to treating hearing loss, generally and a subset are related to FX-322. While we believe that the specific and generic claims contained in some of our issued U.S. patents provide protection for the composition of matter and the method of using FX-322 to treat hearing loss therapies, such as small molecule, antibody, and/or diseases associated with the absence or lack of certain tissue cells, third parties may nevertheless challenge such claims in our patents. If any such claims are invalidated or rendered unenforceable for any reason, we will lose valuable intellectual property rights, and our ability to prevent others from competing with us would be impaired. Any U.S. or ex-U.S. patents that may issue from pending applications that we control, if any, for hearing loss are projected to have a statutory expiration date in between 2035 and 2040, excluding any additional term for patent term adjustments or patent term extensions, if applicable.

In the United States, the term of a patent covering an FDA-approved drug may, in certain cases, be eligible for a patent term extension under the Hatch-Waxman Act as compensation for the loss of patent term during the FDA regulatory review process. The period of extension may be up to five years, but the remaining term of a patent cannot be extended beyond a total of 14 years from the date of product approval. Only one patent among those eligible for an extension and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and in certain other jurisdictions to extend the term of a patent that covers an approved drug. It is possible that issued U.S. patents covering the use of products from our intellectual property may be entitled to patent term extensions. If our use of drug candidates or the drug candidate itself receive FDA approval, we intend to apply for patent term extensions, if available, to extend the term of patents that cover the approved use or drug candidate. We also intend to seek patent term extensions in any jurisdictions where available, however, there is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and, even if granted, the length of such extensions.

protein therapies.

In addition, to patent protection, we rely upon trade secrets, confidential information and know-how, and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and confidential information and know-how are difficult to protect. We seek to protect our proprietary information, in part, using confidentiality agreements with any collaborators, scientific advisors, employees, and consultants; and invention assignment agreements with our employees. We also have agreements requiring assignment of inventions with selected consultants, scientific advisors, and collaborators. These agreements may not provide meaningful protection. These agreements may also be breached, and we may not have an adequate remedy for any such breach. In addition, our trade secrets and/or confidential information and know-how may become known or be independently developed by a third party, or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects many of our products current or obtain potential competitors, either alone or use information that we regard as proprietary. Although we take steps to protect our proprietary information, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information.

Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our drugs or processes, obtain licenses, or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future drugs may have an adverse impact on us. If third parties have prepared and filed patent applications prior to March 16, 2013, in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the United States Patent and Trademark Office, or USPTO, to determine priority of inventions. See "Risk factors—Risks related to our intellectual property" for a more comprehensive description of risks related to our intellectual property.

License and with their collaboration agreements

Astellas Pharma Inc.

In July 2019, we entered into the Astellas Agreement with Astellas, under which we granted Astellas an exclusive, royalty-bearing, sub-licensable, nontransferable license to certain patent rights to research, develop, manufacture, have manufactured, use, seek and secure regulatory approval for, commercialize, offer for sale, sell, have sold and import, and

otherwise exploit licensed products containing both a GSK-3 inhibitor and an HDAC inhibitor, or the Astellas licensed products, including our product candidate FX-322, outside of the United States. We also granted Astellas a right of first negotiation and a right of last refusal if we enter into any negotiation or agreement of any kind (other than an acquisition of all of our stock or assets) with any third party under which such third party would obtain the right to develop, manufacture, or commercialize Astellas licensed products in the United States.

We and Astellas have agreed to jointly develop the Astellas licensed products, including potentially carrying out joint studies. Each party has agreed to use commercially reasonable efforts to carry out development activities assigned to it under an agreed-upon development plan. Astellas has agreed to use commercially reasonable efforts to obtain regulatory approval for at least one Astellas licensed product in SNHL and in age-related hearing loss, in each case, in one major Asian country and one major European country. We have agreed to use commercially reasonable efforts to obtain regulatory approval for at least one Astellas licensed product in the United States. Astellas has the sole right to commercialize the Astellas licensed products outside of the United States, and we have the sole right to commercialize the Astellas licensed products in the United States. Astellas has agreed to use commercially reasonable efforts to commercialize Astellas licensed products in a major Asian country and a major European country following receipt of regulatory approval in such countries.

As consideration for the licensed rights under the Astellas agreement, Astellas paid us an upfront payment of \$80.0 million in July 2019 and has agreed to pay potential development milestone payments up to \$230.0 million. Specifically, we would receive development milestone payments of \$65.0 million and \$25.0 million upon the first dosing of a subject in a Phase 2b clinical trial for SNHL in Europe and Asia, respectively, and \$100.0 million and \$40.0 million upon the first dosing of a subject in a Phase 3 clinical trial for SNHL in Europe and Asia, respectively. If the Astellas licensed products are successfully commercialized, we would be eligible for up to \$315.0 million in potential commercial milestone payments and also tiered royalties at rates ranging from low- to mid-teen percentages.

The Astellas Agreement remains in effect until the expiration of all royalty obligations. Royalties are paid on a licensed product-by-licensed product and country-by-country basis until the latest of (i) the expiration of the last valid claim in the licensed patent rights with respect to such Astellas licensed product in such country or (ii) a set number of years from the first commercial sale of such Astellas licensed product in such country. Astellas may terminate the Astellas Agreement at will upon 60 days' written notice. Each party has the right to terminate the Astellas Agreement due to the other party's material breach if such breach remains uncured for 90 days (or 45 days in the case of nonpayment) or if the other party becomes bankrupt.

Massachusetts Institute of Technology

In December 2016, we entered into an Exclusive Patent License Agreement, or the MIT License, with the Massachusetts Institute of Technology, or MIT, under which we received an exclusive, worldwide, royalty-bearing license to certain patent rights to develop, make, have made, use, sell, offer to sell, lease, and import products, or the MIT licensed products, and to develop and perform processes, or the MIT licensed processes, which incorporate the licensed technology for the treatment of disease, including, but not limited to, the prevention and remediation of hearing loss. We also have the right to grant sublicenses under the MIT License. MIT and Brigham and Women's Hospital retain the right on behalf of themselves and all other nonprofit research institutions to practice the licensed patent rights for nonclinical research, teaching, and educational purposes.

We are required to use diligent efforts to develop and commercialize the MIT licensed products or processes and to make such products or processes reasonably available to the public. We are also subject to certain development obligations with regards to a first MIT licensed product. We have satisfied certain obligations related to preclinical and clinical studies and the filing of an IND for a first MIT licensed product with our development activities related to FX-322. Our future development obligations are: (i) to commence a Phase 3 clinical trial for such Product within five years of the IND filing for such product, (ii) to file a New Drug Application or equivalent with the FDA or comparable European regulatory agency for such Product within nine years of the IND filing for such Product, and (iii) to make a first commercial sale of such Product within 11 years of the IND filing for such Product. We also have certain development obligations with regards to a second MIT licensed product. If we fail to meet our development obligations, other than those relating to a second MIT licensed product, MIT may terminate the MIT License. In the event that we have failed to fulfill our development timeline obligation with respect to a second MIT licensed product and fail to cure such breach within 90 days of written notice by MIT, MIT may restrict the licensed field to the prevention and remediation of hearing loss in humans and animals. We do not have the right to control prosecution of the in-licensed patent applications, and our rights to enforce the in-licensed patents are subject to certain limitations.

Upon entering the MIT License, we paid a \$50 thousand license fee payment and issued to MIT shares of our common stock equal to 5% of our then-outstanding capital stock. We are required to pay certain annual license maintenance fees

ranging from \$30 thousand to \$0.1 million per year prior to first commercial sale of a MIT licensed product and an annual license maintenance fee of \$0.2 million every year afterwards, which may be credited to running royalties during the same calendar year, if any. We are also required to make potential milestone payments in an aggregate amount of up to \$2.9 million on each MIT licensed product or process. In addition, we agreed to pay a low single-digit royalty on the MIT licensed products and processes and a 20% royalty on sub-license revenues.

The MIT License will remain in effect until the expiration or abandonment of all licensed issued patents and filed patent applications, unless terminated earlier. We have the right to terminate for any reason upon three months' prior written notice. MIT has the right to terminate immediately if we cease to carry on any business related to the MIT License. MIT may also terminate the MIT License for our material breach if such breach remains uncured for 90 days (or 30 days in the case of nonpayment). MIT may also terminate the MIT License if we or our affiliates commence any action against MIT to declare or render any claim of the licensed patent rights invalid, unpatentable, unenforceable, or not infringed, or if our sub-licensee commences such actions and we do not terminate such sub-license within 30 days after MIT's demand. MIT has the right to increase all payments due by us, instead of terminating the MIT License in the case of a patent challenge.

In May 2019, we entered into an amendment with MIT, updating the diligence milestones for a second Licensed Product.

In March 2022, we entered into an amendment with MIT, removing a patent and certain patent applications from the MIT License Agreement which were unrelated to our hearing and MS programs and which we were not utilizing.

Massachusetts Eye and Ear (Formerly Massachusetts Eye and Ear Infirmary)

In February 2019, we entered into a Non-Exclusive Patent License Agreement, or the MEE License, with the Massachusetts Eye and Ear, or MEE, under which we received a non-exclusive, non-sub-licensable, worldwide, royalty-bearing license to certain patent rights to develop, make, have made, use, sell, offer to sell, lease and import products and to develop and perform processes that incorporate the licensed technology for the treatment or prevention of hearing loss, or the MEE licensed products. We are obligated to use diligent efforts to develop and commercialize the MEE licensed products. We met one of our milestone timeline obligations by dosing a first subject in a Phase 2 trial by December 31, 2020. We are still subject to a milestone timeline obligation to dose a first subject in a Phase 3 trial by December 31, 2024. We do not control the filing, prosecution, enforcement, and defense of any licensed patent rights.

Upon entering the MEE License, we made a \$20 thousand license fee payment. We are obligated to pay certain annual license maintenance fees between \$5 thousand and \$7.5 thousand per each MEE patent family case number included in the licensed MEE patent rights prior to first commercial sale of an MEE licensed product. We are also obligated to pay a minimum annual royalty payment of \$15 thousand per each MEE patent family case number included in the licensed MEE patent rights after first commercial sale of an MEE licensed product. We are also obligated to make milestone payments up to \$350 thousand on each product or process that incorporates the licensed patent rights. In addition, we have agreed to pay a low single-digit royalty on products and processes that incorporate the licensed patent rights.

The MEE License remains in effect until all issued patents and filed patent applications within the licensed patent rights have expired or been abandoned, unless terminated earlier. We have the right to terminate the MEE License at will by 30 business days' advance written notice to MEE. MEE has the right to terminate the MEE License (i) if we fail to make any payment due within 30 business days after MEE notifies us of such failure, (ii) if we fail to maintain required insurance, (iii) upon 45 business days' written notice if we become insolvent, or (iv) for any other default by us that is not cured within 60 business days of receipt of written notice. MEE also has the right to terminate if we or our affiliates challenge the validity of the licensed patent rights.

The Scripps Research Institute (California Institute for Biomedical Research)

In September 2018, we entered into a license agreement, or the CALIBR License, with the California Institute for Biomedical Research, or CALIBR, a division of Scripps, under which we received an exclusive, worldwide, royalty-bearing license to certain patent rights to make, have made, use, sell, offer to sell, and import products, or the CALIBR licensed products, which incorporate licensed technology for the treatment of MS. We also have the right to grant sublicenses under the CALIBR License. CALIBR reserves the right to use for itself and the right to grant nonexclusive licenses to other nonprofit or academic institutions for any internal research and educational purposes.

We have agreed to use commercially reasonable efforts to develop, manufacture, and sell at least one CALIBR licensed product. We are also subject to certain milestone timeline obligations, which may be extended in certain circumstances as set

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forth in the CALIBR License. In October 2021, we entered into an amendment with CALIBR which updated the milestone obligations to: (i) initiate a Phase 2 clinical trial (or equivalent) for a CALIBR licensed product by December 31, 2023 and (ii) initiate a Phase 3 clinical trial (or equivalent) for a CALIBR licensed product by December 31, 2025. We do not have the right to control prosecution of the in-licensed patent applications, and our rights to enforce the in-licensed patents are subject to certain limitations.

Upon entering the CALIBR license, we made a \$1.0 million license fee payment, and are required to make milestone payments in an aggregate amount of up to \$26.0 million for each category of CALIBR licensed products. Category 1 is any CALIBR licensed products containing a compound that modulates any muscarinic receptor, and Category 2 is any CALIBR licensed products not included in Category 1 that could differentiate oligodendrocyte precursor cells from *in vitro* studies and/or are active in animal models relevant to MS. We are also required to pay a mid-single-digit royalty on CALIBR licensed products and a royalty on sub-license revenues ranging from a low-teen percentage to 50%.

The CALIBR License continues in effect until expiration of all our obligations to pay royalties. Royalties are payable by us on a country-by-country and licensed-product-by-licensed product basis upon the later of (i) the expiration or abandonment of all valid claims of the licensed patent rights in such country and (ii) 10 years from the first commercial sale of each CALIBR licensed product in such country. We may terminate the CALIBR License at will upon 30 days' prior written notice. We may also elect to terminate our license to one or more licensed patents in any or all jurisdictions by giving 90 days' prior written notice to CALIBR. CALIBR may terminate the CALIBR License for our material breach if such breach remains uncured for 30 days. CALIBR has the right to terminate or reduce the license to a non-exclusive license if we fail to use diligent efforts to develop and commercially exploit CALIBR licensed products.

Cambridge Enterprise Limited

In December 2019, we entered into an Exclusive Patent License Agreement, or the Cambridge License, with Cambridge Enterprise, under which we received an exclusive, worldwide, royalty-bearing license to certain patent rights to make, have made, use, sell, offer to sell, and import products, or the Cambridge licensed products, which incorporate licensed technology for the treatment of demyelinating diseases. Under the Cambridge License, we also had the right to grant sublicenses. Upon entering into the Cambridge License, we made a \$50 thousand license fee payment and were obligated to pay an annual license fee of \$50 thousand. On June 28, 2022, we sent Cambridge Enterprise a notice stating that we would be terminating the Cambridge License in 90 days' time, and on September 26, 2022 this termination became effective. We are not subject to any payments or costs as a result of this termination.

Competition

As a clinical-stage biotechnology company, we face competition from a wide array of companies in the pharmaceutical and biotechnology industries. These include both small companies and large companies with much greater financial and technical resources and far longer operating histories than our own. We also compete with the intellectual property, technology, and product development efforts of academic, governmental, and private research institutions.

Our competitors may partners, have significantly greater financial resources established presence in the market, and expertise in research and development, manufacturing, preclinical and testing, conducting clinical testing, obtaining regulatory approvals trials and reimbursement, and marketing approved products than we do. These competitors also compete with us do today. Mergers and acquisitions in recruiting the pharmaceutical, biotechnology and retaining qualified scientific, sales, marketing, and management personnel. establishing clinical trial sites and subject registration for clinical trials, as well as gene therapy industries may result in acquiring technologies complementary to, or necessary for, even more resources being concentrated among a smaller number of our programs, competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The key competitive factors affecting the success of any product candidates that we develop, if approved, are likely We also compete with these companies in recruiting, hiring and retaining qualified scientific and management talent, establishing clinical trial sites and patient registration for clinical trials, obtaining manufacturing slots at contract manufacturing organizations, and in acquiring technologies complementary to, be their efficacy, safety, convenience, price, and the availability of reimbursement from government and other third-party payors, or necessary for, our programs. Our commercial opportunity for any of our product candidates could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, particularly if they represent cures, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, and may commercialize products more quickly than which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our programs are likely to be their efficacy, safety, convenience, and availability of reimbursement.

Intellectual Property

Overview

We strive to protect the proprietary technology that we believe is important to our business, including seeking and maintaining patent protection in the United States and internationally for our current and future product candidates. We also rely

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on trademarks, copyrights, trade secrets, confidentiality procedures, employee disclosure, invention assignment agreements, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

We seek to obtain domestic and international patent protection, and endeavors to promptly file patent applications for new commercially valuable inventions. We also rely on trade secrets to protect aspects of our business that are multiple therapeutic options not amenable to, or that we do not consider appropriate for, treating patent protection.

We plan to continue to expand our intellectual property estate by filing patent applications directed to platform technologies and improvements thereof, pharmaceutical compositions, methods of treatment, methods of manufacture or identified from our ongoing development of our product candidates. Our success will depend on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce any patents that we may obtain, preserve the symptoms confidentiality of MS, our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties.

The patent positions of companies like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent may be challenged in courts after issuance. Moreover, many jurisdictions permit third parties to challenge issued patents in administrative proceedings, which may result in further narrowing or even cancellation of patent claims. We cannot guarantee that our pending patent applications, or any patent applications that we may in the future file or license from third parties, will result in the issuance of patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or at all, whether the claims of any patent applications, should they issue, will cover our product candidates, or whether the claims of any issued patents will provide sufficient protection from competitors or otherwise provide any competitive advantage. We cannot predict the scope of claims that may be allowed or enforced in our patents. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our product candidates.

Because patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months or potentially even longer, and because publication of discoveries in the scientific or patent literature often lags behind actual discoveries and patent application filings, we cannot be certain of the priority of inventions covered by pending patent applications. Accordingly, we may not have been the first to invent the subject matter disclosed in some of our patent applications or the first to file patent applications covering such subject matter, and we may have to participate in interference proceedings or derivation proceedings declared by the USPTO to determine priority of invention. For more information regarding the risks related to our intellectual property, see Item 1A "Risk Factors—Risks Related to Our Business—Risks Related to Intellectual Property."

Patent Portfolio

We strive to protect our proprietary RNA editing platform OPERA and related technologies and our product candidates, including seeking and maintaining patent protection intended to cover various target-specific editing strategies, the composition of matter of our product candidates, their methods of use, related delivery technologies, and other inventions. The intellectual property that is available to us is critical to our business and we strive to protect it, including by obtaining, maintaining, defending, and enforcing patent protection in the United States and internationally. As of December 31, 2023, our patent portfolio in total consisted of 32 patent families, with two U.S. patents and one patent in foreign jurisdictions (e.g., Canada), including five pending Patent Cooperation Treaty, or PCT, applications, various pending non-provisional applications world-wide (e.g., United States, Australia, Canada, China, Europe, South Korea, and Japan), and nine families with pending provisional patent applications.

We have a patent portfolio that relates to our RNA editing platform OPERA, as well as the underlying disease. However, all approved therapies numerous disease programs listed below, and includes 13 patent families. These families are directed at blocking demyelination, to various oligonucleotide formats, nucleotide compositions, oligonucleotide chemistries, modifications, specific linkage chemistries, oligonucleotides having a specific structures, methods of deaminating an adenosine using such oligonucleotides, methods of

oligonucleotide delivery, and methods of treating disease by administering such oligonucleotides. The first patent family is pending in Australia, Canada, China, Europe, Japan, South Korea, Taiwan and the United States, and includes a U.S. patent. The first three patent families are pending in Australia, Canada, China, Europe, Hong Kong, Japan, South Korea, Taiwan and the United States, and include two U.S. patents. U.S. Patent No. 11,479,575 is directed to our knowledge, there are no approved therapies that are designed specific oligonucleotide structures and expires in 2040; U.S. Patent No. 11,453,878 is directed to promote remyelination. We are aware methods of numerous efforts to identify drugs deamination of an adenosine in an mRNA using oligonucleotide with specific structures and also expires in 2040. Any other patents issuing from applications in these families will expire in 2040, absent any available additional term for patent term extension or biologics that can stimulate patent term adjustment. The fourth patent family is pending in the United States and patents issuing from applications in this family will expire in 2042, absent any available additional term for patent term extension or patent term adjustment. The fifth, sixth, seventh and eighth patent families have been filed as PCT applications, and if issued, patents in these families would expire between 2042 and 2043, absent any available additional term for patent term extension or patent term

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adjustment. The ninth, tenth, eleventh, twelfth and myelin repair thirteenth patent families have been filed as provisional patent applications, and if re-filed as PCT or non-provisional applications, and issued, patents in this family would expire in 2044, absent any available additional term for patent term extension or patent term adjustment.

In addition to the patent families related to our OPERA platform technology described above, our patent portfolio that relates to our AAT program includes two patent families. These patent families are directed to specific oligonucleotides that target SERPINA1 for editing to treat AAT. The first patent family includes pending applications in Australia, Canada, China, Europe, Japan, South Korea and the United States. Patents issuing from applications in this family will expire in 2041, absent any available additional term for patent term extension or patent term adjustment. The second patent family has been filed as a provisional patent application, and if re-filed as PCT or non-provisional applications, and issued, patents in this family would expire in 2044, absent any available additional term for patent term extension or patent term adjustment.

In addition to the patent families related to our OPERA platform technology described above, our patent portfolio that relates to our PD program includes one patent family. This patent family is directed to specific oligonucleotides that target LRRK2 for editing to treat PD, and includes pending applications in Europe, and the United States. Patents issuing from applications in this family will expire in 2041, absent any available additional term for patent term extension or patent term adjustment.

In addition to the patent families related to our OPERA platform technology described above, our patent portfolio that relates to our SAH program includes two patent families. This patent family is directed to specific oligonucleotides that are capable of editing a specific target associated with SAH, and consists of a pending PCT application. Patents issuing from this family of patent applications will expire in 2042, absent any available additional term for patent term extension or patent term adjustment. The second patent family has been filed as a provisional patent application, and is directed to specific oligonucleotides that are capable of editing a specific target associated with SAH. If this application is re-filed as an PCT or non-provisional application, and issued, patents in this family will expire in 2043, absent any available additional term for patent term extension or patent term adjustment.

In addition to the patent families related to our OPERA platform technology described above, our patent portfolio that relates to our ALS includes one patent family, directed to oligonucleotides that edit TDP-43. This patent family consists of two provisional patent applications, and if re-filed as PCT or non-provisional applications, and issued, patents in this family would expire in 2044, absent any available additional term for patent term extension or patent term adjustment.

In addition to the patent families described above, we also have other patent families directed to additional target-specific editing strategies, oligonucleotide compositions and their methods of use, related delivery technologies, and other inventions related to early-stage research and development efforts not reflected in our pipeline. Patents issued from or issuing from applications in these families will expire between 2041 and 2044, absent any available additional term for patent term extension or patent term adjustment, and includes Canadian Patent No. 3,162,416, which will expire in 2042. We also have legacy patents related to our pre-Merger operations.

Patent Term

The term of individual patents depends upon the legal term of the patents in the central nervous system. These include companies such as Clene Inc., countries in which has an ongoing Phase 2 trial of CNM-Au8, a gold nanocrystal suspension, and Pipeline Therapeutics, they are obtained. In most countries in which completed a Phase 1 trial for PIPE-307, a selective M1 receptor antagonist to treat multiple sclerosis and other demyelinating disorders. In March 2022, Pipeline received IND clearance to initiate a Phase 1b/2a study of PIPE-307. Idorsia Pharma completed two Phase 1 studies in 2019 and 2020 for ACT-1004-1239, a small molecule CXCR7 inhibitor involved in OPC differentiation. NervGen Pharma we file, including the United States, the base term is developing NVG-291, a therapeutic peptide which is a mimetic 20 years from the filing date of the intracellular domain earliest-filed non-provisional patent application from which the patent claims priority. The term of protein tyrosine phosphatase (PTP α), a U.S. patent can be lengthened by patent term adjustment, which compensates the owner of the patent for administrative delays at the USPTO. In October 2022, NervGen Pharma announced plans some cases, the term of a U.S. patent is shortened by terminal disclaimer that reduces its term to initiate that of an earlier-expiring patent. The term of a Phase 2 trial U.S. patent may be eligible for patent term extension under the Drug Price Competition and Patent Term Restoration Act of NVG-291 in 2023 in patients 1984, referred to as the Hatch-Waxman Act, to account for at least some of the time the drug is under development and regulatory review after the patent is granted. With regard to a drug for which FDA approval is the first permitted

marketing of the active ingredient, the Hatch-Waxman Act allows for extension of the term of one U.S. patent that complies with **RRMS**, applicable FDA or other requirements at any time with respect to product development, clinical testing, approval or any other regulatory requirements relating to product manufacture, processing, handling, storage, quality control, safety, marketing, advertising, promotion, packaging, labeling, export, import, distribution, or sale.

This We may become subject to administrative or judicial sanctions or other legal consequences. These sanctions or consequences could include, among other things, the FDA's refusal to approve pending applications, issuance of clinical holds for ongoing studies, suspension or revocation of approved at least one claim covering the composition of matter of such an FDA-approved drug, an FDA-approved method of treatment using the drug and/or a method of manufacturing the FDA-approved drug. The extended patent term cannot exceed the shorter of five years beyond the non-extended expiration of the patent or 14 years from the date of the FDA approval of the drug, and a patent cannot be extended more than once or for more than a single product. During the period of extension, if granted, the scope of exclusivity is **an active research area with a number of entities researching compounds, antibodies, and proteins which may enhance remyelination**, limited to the approved product for approved uses. Some

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foreign jurisdictions, including Europe and Japan, have analogous patent term extension provisions, which allow for extension of the term of a patent that covers a drug approved by the applicable foreign regulatory agency.

In the future, if and when our product candidates receive FDA approval, we expect to apply, if appropriate, for patent term extension on patents directed to those product candidates, their methods of use and/or methods of manufacture. However, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions. For more information regarding the risks related to our intellectual property, see Item 1A "Risk Factors—Risks Related to Our Business—Risks Related to Intellectual Property."

Reservation of Rights by the U.S. Government

Our in-licensed patent rights may be subject to a reservation of rights by one or more third parties, including the U.S. government. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. When new technologies are developed with government funding, in order to secure ownership of patent rights related to the technologies, the recipient of such funding is required to comply with certain government regulations, including timely disclosing the inventions claimed in such patent rights to the U.S. government and timely electing title to such inventions. A failure to meet these obligations may lead to a loss of rights or the unenforceability of relevant patents or patent applications. In addition, the U.S. government has the right, under certain limited circumstances, to require the licensor to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). Recent developments in regarding the Bayh-Dole Act of 1980 indicate that the march-in rights could be exercised to affect pricing.

If the U.S. government exercised its march-in rights in our future intellectual property rights that are generated through the use of U.S. government funding or grants, we could be forced to license or sublicense intellectual property that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. If the U.S. government decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. The U.S. government's rights may also permit it to disclose the funded inventions and technology, which may include our confidential information, to third parties and to exercise march-in rights to use or allow third parties to use the technology that was developed using U.S. government funding. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. For more information regarding the risks related to our intellectual property, see Item 1A "Risk Factors—Risks Related to Our Business—Risks Related to Intellectual Property."

Trade Secrets

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. We typically rely on trade secrets to protect aspects of our business that are not amenable to, or that we not consider appropriate for, patent protection. We protect trade secrets and know-how by establishing confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and collaborators. These agreements provide that all confidential information developed or made known during the course of an individual or entities' relationship with us must be kept confidential during and after the relationship. These agreements also provide that all inventions resulting from work performed for us or relating to our business and conceived or completed during the period of employment or assignment, as applicable, shall be our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary information by third parties.

Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. For more information regarding the risks related to our intellectual property, see Item 1A "Risk Factors—Risks Related to Our Business—Risks Related to Intellectual Property."

Governmental Regulation

The FDA and comparable other regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome requirements upon companies involved in the clinical development, manufacture, marketing, and distribution of drugs, such as those we are developing. These agencies and other at federal, state and local entities levels, as well as in foreign countries, extensively regulate, among other things, the research, and development, clinical trial, testing, manufacture, quality control, import, export, safety, effectiveness, efficacy, labeling, packaging, storage, record keeping, distribution, recordkeeping, approval, distribution, advertising, and promotion, distribution, marketing, post-approval monitoring and post-approval reporting sampling, of drugs. We, along with our vendors, CROs, clinical investigators and export CMOs will be required to navigate the various preclinical, clinical, manufacturing and import commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of our product candidates.

U.S. drug development process

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process of obtaining regulatory approvals of drugs and the ensuring subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure

Overview of U.S. Drugs Development Process

In the United States, the FDA regulates drug products under the FD&C Act and its implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. If we fail to comply with the applicable U.S. FDA or other requirements at any time during the with respect to product development, process, clinical testing, approval process, or after approval, any other legal requirements relating to product manufacture, processing, handling, storage, quality control, safety, marketing, advertising, promotion, packaging, labeling, export, import, distribution, or sale, we may become subject an applicant to a variety of administrative or judicial sanctions such as or other legal consequences. These sanctions or consequences could include, among other things, the FDA's refusal to approve pending new drug applications, NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning or untitled letters, product withdrawals or recalls, product seizures, relabeling or repackaging, total or partial suspension suspensions of production manufacturing or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil penalties or criminal penalties, prosecution.

The process required Our product candidates must be approved for therapeutic indications by the FDA before a drug they may be marketed in the United States States. For drug product candidates regulated under the FD&C Act, FDA must approve a NDA. The process generally involves the following:

- completion of extensive preclinical laboratory tests and formulation studies, as well as animal safety studies in compliance accordance with the FDA's applicable regul including studies conducted in accordance with good laboratory practice, or GLP, regulations, as appropriate; requirements and applicable requirements for the humar of laboratory animals or other applicable regulations;
- completion of the manufacture, under cGMP conditions, of the drug substance and drug product that the sponsor intends to use in human clinical trials along with req analytical and stability testing;
- submission to the FDA of an IND which must become effective before human clinical trials may begin;
- payment of user fees for FDA review of the NDA;
- approval by an IRB or independent institutional review board, or IRB, ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good applicable IND regulations, GCP requirements and other clinical practice, o requirements trial-related regulations to establish the safety and efficacy of the proposed drug investigational product for each proposed indication;
- preparation and submission to the FDA of an NDA;
- endorsement a determination by the FDA within 60 days of its receipt of an FDA advisory committee, if applicable; NDA to file the application for review;
- satisfactory completion of an one or more FDA inspection of the clinical site(s), and related services involved in the conduct of the clinical studies to assess complianc good clinical practices, or GCP;
- satisfactory completion of an FDA inspection pre-approval inspections of the manufacturing facility or facilities at which where the product is drug will be produced to as compliance with current good manufacturing practice, or cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the drug product's identity, strength, quality and purity;
- satisfactory completion of potential FDA audit of the preclinical study clinical trial sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA, including, where applicable, consideration of the views of any FDA advisory committee, prior to any commercial marketing or sa the drug in the United States; and States.

compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, or to conduct a post-approval study or studies.

Preclinical studies³³

Preclinical Studies and Clinical Trials for Drugs

Before testing any drug in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluation of product chemistry, toxicity, formulation and formulation, stability, as well as *in vitro* and animal studies to assess potential safety and efficacy. An IND sponsor must submit in some cases to establish the rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulation and requirements, including GLP requirements for safety/toxicology studies. The results of the preclinical tests, studies, together with

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manufacturing information and analytical data, and any available clinical data or literature, among other things, must be submitted to the FDA as part of an IND.

An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before clinical trials may begin. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical trials. The IND also includes the results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. Some long-term preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that the FDA, within the 30-day time the FDA period, raises concerns or questions related to about the submission including to one or more proposed clinical trials and places conduct of the clinical trial, on including concerns that human research subjects will be exposed to unreasonable health risks, and imposes a partial full or full partial clinical hold. In such a case, the IND sponsor and the FDA must resolve notify the sponsor of the grounds for the hold and any outstanding concerns identified deficiencies must be resolved before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns about on-going or proposed clinical trials or noncompliance with specific FDA requirements, and the trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted. As a result, submission Submission of an IND may not result in the FDA not allowing clinical trials to commence, commence or not allowing clinical trials to commence on the terms originally specified in the IND. A clinical hold can also be imposed once a trial has already begun, thereby halting the trial until the deficiencies articulated by FDA are corrected.

Clinical trials

Clinical trials involve The clinical stage of development involves the administration of the investigational new drug product candidate to human subjects healthy volunteers or patients under the supervision of qualified investigators, who generally are physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement requirements that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters and criteria to be used in monitoring safety and the effectiveness criteria to be evaluated. A evaluating effectiveness. Each protocol, for each clinical trial and any subsequent amendments to the protocol, amendments must be submitted to the FDA as part of the IND. In addition, Furthermore, each clinical trial must be reviewed and approved by an IRB at for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trial trials are minimized and are reasonable compared to the anticipated benefits. The IRB also approves the informed consent form that must review and approve the plan for any be provided to each clinical trial before it commences at that institution. Information about certain clinical trials subject or his or her legal representative and must be submitted within specific time frames to monitor the National Institutes of Health, or NIH, for public dissemination on their www.clinicaltrials.gov website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- Phase 1: The drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption metabolism, distribution, excretion, and, if possible, to gain an early indication of its effectiveness.
- Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product specific targeted diseases, and to determine dosage tolerance and optimal dosage.
- Phase 3: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate until completed. The FDA, the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

The FDA IRB, or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unreasonable unacceptable health risk. Similarly, an IRB can suspend or terminate approval There also are requirements governing the reporting of ongoing clinical trials and completed clinical trials to public registries. Information about clinical trials, including results for clinical trials other than Phase 1 investigations, must be submitted within specific timeframes for publication on www.ClinicalTrials.gov, a clinical trial at its institution if trials database maintained by the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, National Institutes of Health.

Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether or not a clinical trial may move forward at designated check points based on access that only the group maintains to certain available data from the trial and may recommend halting the clinical trial if it determines that the participants or patients are being exposed to an unacceptable health risk or other grounds, such as no demonstration of efficacy. Other reasons for suspension or termination may be made by us based on evolving business objectives and/or competitive climate.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, FDA will nevertheless accept the results of the study in support of an NDA if the study was well-designed and well-conducted in accordance with GCP requirements, including that the clinical trial was performed by a qualified investigator(s); the data are applicable to the U.S. population and U.S. medical practice; and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials to evaluate therapeutic indications to support NDAs for marketing approval are typically conducted in three sequential phases, which may overlap.

- **Phase 1** – Phase 1 clinical trials involve initial introduction of the investigational product in a limited population of healthy human volunteers or patients with the target disease or condition. These studies are typically designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, excretion the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.
- **Phase 2** – Phase 2 clinical trials typically involve administration of the investigational product to a limited patient population with a specified disease or condition to evaluate the drug's potential efficacy, to determine the optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks.

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- **Phase 3** – Phase 3 clinical trials typically involve administration of the investigational product to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval and physician labeling. Generally, two adequate and well-controlled Phase 3 trials are required by the FDA for approval of an NDA.

Post-approval trials, sometimes referred to as Phase 4 clinical trials or post-marketing studies, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of NDA approval.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA. Written IND safety reports must be submitted to the FDA and the investigators fifteen days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human volunteers and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information. During the development of a new drug product, sponsors have the opportunity to meet with the FDA at certain points, including prior to submission of an IND, at the end of Phase 2 and before submission of an NDA. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date and for the FDA to provide advice on the next phase of development.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug product candidate and finalize a process for manufacturing the drug product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and manufacturers must develop, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, drug product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA, U.S. Review and more frequently if serious adverse events occur. Phase 1, Phase 2, and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. There are also requirements governing the registration of, reporting of ongoing clinical trials and completed trial results to public registries.

Marketing approval

Approval Process for Drugs

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical studies, trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. An NDA is a request for approval to market a new drug for one or more specified indications and must contain proof of the drug's safety and efficacy for the requested indications. The marketing application is required to include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational drug, to the satisfaction of the FDA. FDA must approve an NDA before a drug may be marketed in the United States.

indications. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes 12 months from the date the NDA is submitted to the FDA because the FDA has approximately two months to make a "filing" decision. Specifically, the FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA review before it accepts them for filing and may request additional information rather than accepting the NDA for filing. The FDA must make a decision on accepting an NDA for filing. In this event, filing within 60 days of receipt, and such decision could include a refusal to file by the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. FDA. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the NDA. The FDA reviews an NDA to determine, among other things, whether the submitted information supports that the drug product is safe and effective for the indications sought and whether the facility in which it is manufactured, processed, packaged or held meets standards, including cGMP requirements, designed to assure and preserve the product's continued safety, identity, strength, quality and purity. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA targets ten months, from the filing date, in which to complete its initial review of a new molecular entity NDA and respond to the applicant, and six months from the filing date of a new molecular entity NDA for priority review. The FDA does not always meet its PDUFA goal dates for standard or priority NDAs, and the review process is often extended by FDA requests for additional information or clarification.

Further, under PDUFA, as amended, each NDA must be accompanied by a substantial user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA also may require submission of a REMS plan if it believes that a REMS is necessary to ensure that for certain medications with serious safety concerns the benefits of the drug outweigh its risks. The REMS plan could include use of risk evaluation and mitigation strategies like medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, special monitoring or other risk minimization risk-minimization tools.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements and other requirements and the integrity of the clinical data submitted to the FDA.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a Complete Response Letter. A Complete Response Letter or CRL indicates that the review cycle of the application is complete and the application is not ready for approval. A CRL Complete Response Letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA, and except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response Letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response Letter, the FDA may require additional clinical or preclinical testing or recommend other actions, such as requests for additional information or clarification, that the applicant might take in order for the FDA to reconsider the application for approval. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug product with specific prescribing information for specific indications.

Even if the FDA approves a product, depending on the specific risk(s) to be addressed it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's product's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is a disease or condition with either a patient population of fewer than 200,000 individuals in the United States, or a patient population of 200,000 or more individuals in the United States when there is no reasonable expectation that the cost of developing and making the product available in the United States for the disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, though companies developing orphan products are eligible for certain incentives, including tax credits for qualified clinical testing and user-fee waivers.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to a seven-year period of marketing exclusivity during which the FDA may not approve any other applications to market the same therapeutic agent for the same indication, except in limited circumstances, such as a subsequent product's showing of clinical superiority over the product with orphan exclusivity or where the original applicant cannot produce sufficient quantities of product. Competitors, however, may receive approval of different therapeutic agents for the indication for which the orphan product has exclusivity or obtain approval for the same therapeutic agent for a different indication than that for which the orphan product has exclusivity. Orphan product exclusivity could block the approval of one of our products for seven years if a competitor obtains approval for the same therapeutic agent for the same indication before we do, unless we are able to demonstrate that our product is clinically superior. If an orphan designated product receives

The Pediatric Research Equity Act, or PREA, requires a sponsor

marketing approval for an indication broader than what is designated, it may not be entitled to conduct pediatric clinical trials orphan exclusivity. Further, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver, designation was materially defective or the indication sought manufacturer of the approved product is for an orphan condition. The required assessment must evaluate the safety and effectiveness unable to assure sufficient quantities of the product for to meet the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which needs of patients with the product is safe and effective. The sponsor rare disease or the FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a noncompliance letter to any sponsor that fails to submit the required assessment, keep a deferral current, or fails to submit a request for approval of a pediatric formulation. In some situations, the requirement for studies in pediatric populations can be waived if there is no relevant use.

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FDA-expedited development and review programs

condition.

The FDA has various programs, including may further reevaluate its regulations and policies under the Orphan Drug Act. It is unclear as to how, if at all, the FDA may change the orphan drug designation, rare pediatric disease designation, fast track designation, accelerated approval priority review, regulations and breakthrough therapy designation, which are policies in the future.

Expedited Development and Review Programs for Drugs

The FDA maintains several programs intended to facilitate and expedite or simplify the process for the development and the FDA review of new drugs that are intended for to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions conditions. These programs include Fast Track designation, Breakthrough Therapy designation, Priority Review and demonstrate Accelerated Approval, and the potential to address unmet medical needs. The purpose of these programs is to provide either expedite the development or review of important new drugs to get them to patients earlier more quickly than under standard FDA review procedures. timelines typically permit.

To be A new drug is eligible for a fast track Fast Track designation the FDA must determine, based on the request of a sponsor, that a product if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need, needs for such disease or condition. Fast track designation applies to the combination of the product candidate and the specific indication for which it is actively developing being studied. Fast Track designation provides increased opportunities for sponsor interactions with the drug FDA during preclinical and clinical development, in addition to the potential for the disease. The FDA will determine rolling review once a marketing application is filed. Rolling review means that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. The the FDA may review sections portions of the NDA for a fast track product on a rolling basis marketing application before the sponsor submits the complete application application.

In addition, a new drug may be eligible for Breakthrough Therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug, alone or in combination with one or more other drugs, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy designation provides all the features of Fast Track

designation in addition to intensive guidance on an efficient product development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any product submitted to the FDA for approval, including a product with Fast Track or Breakthrough Therapy designation, may also be eligible for additional FDA programs intended to expedite the review and approval process, including Priority Review designation and Accelerated Approval. A product is eligible for Priority Review, once an NDA is submitted, if the sponsor provides a schedule for product that is the submission subject of the sections marketing application has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

The FDA may give a serious disease or condition. Under priority review, designation the FDA's goal date to drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists. A priority review means that take action on the goal for the FDA to review an marketing application is six months rather than the compared to ten months for a standard review of 10 months under current PDUFA guidelines. Under the new PDUFA agreement, these six- and 10-month review periods are measured from the "filing" date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that review.

Products are eligible for fast track designation are also likely Accelerated Approval if they can be shown to be considered appropriate to receive a priority review, and, if relevant, accelerated approval.

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, that which is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As Accelerated Approval is usually contingent on a condition of approval, the FDA may require sponsor's agreement to conduct, in a sponsor of a drug receiving accelerated approval to perform post-marketing diligent manner, adequate and well-controlled additional post-approval confirmatory studies to verify and describe the predicted effect on irreversible morbidity or mortality or other product's clinical endpoint, benefit, and the drug may be subject to accelerated withdrawal procedures.

Moreover, under the provisions of the Food and Drug Administration Safety and Innovation Omnibus Reform Act of 2022, or FDASIA, passed in July 2012, FDORA, the FDA may require, as appropriate, that such trials be underway prior to approval or within a sponsor can request designation specific time period after the date of approval for a product granted accelerated approval. Further, under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug or an indication approved under Accelerated Approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, for products being considered for Accelerated Approval, the FDA generally requires, unless otherwise informed by the agency, that is all advertising and promotional materials intended alone for dissemination or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for priority review and accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review publication within 120 days of an application for marketing approval of a breakthrough therapy. The designation includes all the benefits of a fast track designation. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted submitted to the same drug if relevant criteria are met.

agency for review during the pre-approval review period. After the 120-day period has passed, all advertising and promotional materials must be submitted at least 30 days prior to the intended time of initial dissemination or publication.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will may not be shortened. Furthermore, fast track Fast Track designation, priority review, Breakthrough Therapy designation, Priority Review and breakthrough therapy designation Accelerated Approval do not change the scientific or medical standards for approval but or the quality of evidence necessary to support approval, though they may expedite the development or approval review process. We may explore some of these opportunities for our product candidates as appropriate.

Post-approval requirements³⁷

U.S. Post-Approval Requirements for Drugs

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion, and reporting of adverse experiences with the product. After approval, most changes product, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities.

Although physicians may prescribe approved products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, including not only by company employees but also by agents of the company or those speaking on the company's behalf, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Promotional materials for approved drugs must be submitted to the approved product, such as adding FDA in conjunction with their first use or first publication. Further, if there are any modifications to the drug, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new indications NDA or other labeling claims, are subject to prior FDA review NDA supplement, which may require the development of additional data or preclinical studies and

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approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing post-market testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug manufacturers and other entities their subcontractors involved in the manufacture and distribution of approved drugs and those supplying products, ingredients and components of them, are required to register their establishments with the FDA and certain state and local agencies and are subject to periodic unannounced inspections by government the FDA and certain state agencies for compliance with cGMP ongoing regulatory requirements, including cGMPs, which impose certain procedural and other requirements, documentation requirements on sponsors and their CMOs. Changes to the manufacturing process are strictly regulated, and, often depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor us and any third-party manufacturers that the a sponsor may decide to use. Additionally, manufacturers and other parties involved in the drug supply chain for prescription drugs must also comply with product tracking and tracing requirements and for notifying FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. Accordingly, manufacturers must continue to expend time money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. Failure to comply with statutory and regulatory requirements may subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, product seizures, injunctions, civil penalties or criminal prosecution. There is also a continuing, annual program user fee for any marketed product.

Once an approval is granted, the The FDA may withdraw the approval of a product if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of information, requirements for post-market studies or clinical trials to assess new safety risks; risks, or imposition of distribution or other restrictions under a REMS program. REMS. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warning warnings or other safety information about product;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs applications or supplements to approved NDAs, applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties, penalties;

The FDA strictly regulates marketing,

• consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs; and

- mandated modification of promotional materials and labeling advertising, and promotion issuance of products that are placed on the market. Drugs may be promoted (the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibitir promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. corrective information.

In addition, 38

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the distribution timing, duration and specifics of prescription pharmaceutical products FDA approval of our future product candidates, some of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during the FDA regulatory review process. Patent term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. The patent term restoration period is subject generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the Prescription Drug Marketing Act, expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or PDMA, which regulates restoration. In the distribution future, we may apply for restoration of drugs patent term for our currently owned or licensed patents to add patent life beyond a patent's current expiration date, depending on the expected length of the clinical trials and drug samples at other factors involved in the federal level and sets minimum standards for filing of the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. relevant NDA.

Marketing exclusivity

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain marketing drug product applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application, Abbreviated New Drug Application, or ANDA, or an NDA submitted under Section 505(b)(2), or a 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless version of whether the such drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

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non-infringement. The FDCA alternatively also provides three to five years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval based on conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the original active agent for the original indication or condition of use. agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Privacy and Cybersecurity

Pediatric exclusivity is another type Our operations entail the collection, use, disclosure, transfer, and processing of marketing exclusivity available sensitive and personal information. These operations subject us to privacy and data security laws and regulations in the United States. Pediatric exclusivity provides States and internationally, including, for an additional six months example and depending on the particular activity, the EU General Data Protection Regulation, or EU GDPR, as the GDPR as incorporated into the laws the United Kingdom, or UK GDPR, and together with EU GDPR, GDPR, and other laws, rules and regulations designed to regulate the processing of marketing exclusivity attached personal information and for example reduce risks of identity theft. The privacy, data protection and data security laws to another period which we are subject impose obligations with respect to the collection, processing, storage, disposal, use, transfer, retention and disclosure of exclusivity personal information. In addition, under certain of these laws, we must provide notice to individuals of our policies and extends patent life practices for sharing personal information with third parties, provide advance notice of any changes to our policies and in some cases give individuals the right to prevent processing of their personal information and disclosure of it to third parties. Our operations extend to commercial partnerships and third-party processors, each of which may be governed by their distinct privacy regulations and data security laws. These laws are constantly evolving and subject to varying interpretations, requiring us to periodically update our policies and measures to maintain compliance.

The GDPR in the EU and the UK, which have been incorporated into their respective laws, impose stringent requirements on the processing of health and other sensitive data. These requirements encompass: (i) providing information to individuals regarding data processing activities; (ii) ensuring a related patent if a sponsor conducts legal basis or condition applies to the processing of personal data and, where applicable, obtaining consent from individuals to whom the data processing relates; (iii) responding to data subject requests; (iv) imposing requirements to notify the competent national data protection authorities and data subjects of personal data breaches; (v) implementing safeguards in connection with the security and confidentiality of the personal data; (vi) accountability requirements; and (vii) taking certain measures when engaging third-party processors. The GDPR is also the regulation that informs our obligations with respect to any clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials.

Other healthcare laws and compliance requirements

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities conducted in the state, local, EEA or UK. The GDPR's definition of personal data includes coded data, and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, U.S. federal it requires changes to informed consent practices and state anti-kickback, fraud detailed notices for clinical trial subjects and abuse, false claims, consumer fraud, pricing

reporting, and transparency laws and regulations, as well as similar foreign laws in the jurisdictions outside the U.S. State laws may require pharmaceutical companies investigators. Failure to comply with the pharmaceutical industry's voluntary GDPR can result in significant practical, legal, and financial repercussions, including the destruction of improperly gathered or used personal data, substantial fines of up to €20 million (£17.5 million) or 4% of the

company's global annual turnover, mandatory audits, orders to cease or modify data use, and a private right of action enabling data subjects to seek damages. In addition, the GDPR provides that EU member states or the UK may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric, or health data.

Further, the UK has recently introduced a new Data Protection & Digital Information (No. 2) Bill. This development could reshape the UK's data protection landscape, distancing it from the EU's data protection regime. This lack of clarity on future UK laws and regulations and their interaction with those of the EU could add legal risk, uncertainty, complexity, and cost; and any resulting divergence in laws could increase our risk profile and necessitate further compliance guidelines measures.

To enable the transfer of personal data outside of the EU or the UK, adequate safeguards must be implemented in compliance with the GDPR. The European Commission has issued standard contractual clauses, or SCCs, for data transfers from controllers or processors in the EU (or otherwise subject to the GDPR) to controllers or processors established outside the EU (and not subject to the GDPR). The UK is not subject to the European Commission's new SCCs, and instead it has published the UK International Data Transfer Agreement, or IDTA, and the relevant compliance guidance promulgated by International Data Transfer Addendum to the federal government, new SCCs, or the Addendum, which enable transfers from the UK. Companies relying on SCCs or the IDTA to govern transfers of personal data to third countries will also need to assess whether the data importer can ensure sufficient guarantees for safeguarding the personal data under GDPR, including an analysis of the laws in the recipient's country. Further, the EU and United States have adopted its adequacy decision for the EU-U.S. Data Privacy Framework, or the Framework, which entered into force on July 11, 2023. The Framework provides that the protection of personal data transferred between the EU and the United States is comparable to that offered in the EU. This provides a further avenue to ensuring transfers to the United States are carried out in line with EU GDPR. There has been an extension to the Framework to cover UK transfers to the United States. The Framework could be challenged like its predecessor frameworks. When conducting restricted data transfers under the EU and UK GDPR, we will need to implement these new safeguards, and doing so will require significant effort and cost.

Failure to implement valid mechanisms for personal data transfers from Europe may result in increased exposure to regulatory actions, substantial fines and injunctions against processing personal data from Europe. Inability to export personal data may also: (i) restrict our activities outside Europe; (ii) limit the ability to collaborate with partners as well as other service providers, contractors and other companies outside of Europe; and/or (iii) require us to increase our processing capabilities within Europe at significant expense or otherwise cause us to change the registration geographical location or segregation of pharmaceutical sales representatives our relevant systems and operations – any or all of which could adversely affect our operations or financial results.

In the United States, privacy and security of personal information are regulated by various federal and state laws, such as health information privacy laws, security breach notification laws, and consumer protection laws.

Compliance with these multifaceted privacy and data security laws can be time-consuming, and failure to comply with any of these regulations could lead to significant fines and penalties (potentially including criminal prosecution), adversely affecting our reputation, business, financial condition, and operational results. Changes in statutes, regulations, or interpretations of existing regulations could impose additional requirements on our operations, such as modifications to data processing arrangements, changes to privacy policies, recall or discontinuation of certain data processing methods, or additional recordkeeping requirements. These changes could adversely affect the operation of our business.

There is a further risk that we may not be able to adequately protect our information systems from cyberattacks. Such breaches could result in the disclosure of confidential, protected, or personal information, damage our reputation, and expose us to significant financial and legal exposure, including potential civil fines and penalties, litigation, and regulatory investigations or enforcement actions under laws such as HIPAA and the reporting GDPR. Further, all 50 states in the United States have laws including obligations to provide notification of pricing unauthorized acquisition of personal information to affected individuals, state officers and marketing expenditures. Violations others. Some laws may also impose physical and electronic security requirements regarding the safeguarding of such personal information. In order to comply with privacy and information security laws, we have confidentiality and information security standards and procedures in place for our business activities.

In addition to the risks outlined above, the legal or any regulatory actions may also divert our management from their primary operations. Prohibitions, restrictions, or allegations of violations of these laws could materially and adversely affect our business. Hence, ensuring consistent compliance with privacy and data security laws and regulations remains a critical operational imperative for us.

Other Regulatory Matters

Manufacturing, labeling, packaging, distribution, sales, promotion and other governmental regulations that apply, activities of product candidates following product approval, where applicable, or commercialization are also potentially subject to federal and state consumer protection and unfair competition laws, among other requirements to which we may result be subject. Additionally, the activities associated with the commercialization of product candidates are subject to regulation by numerous regulatory authorities in penalties, including, without limitation, civil the United States in addition to the FDA, which may include the Centers for Medicare and criminal penalties, damages, fines, additional reporting

and oversight obligations, Medicaid Services, or CMS, other divisions of the curtailment or restructuring of operations, exclusion from participation in governmental healthcare programs, and individual imprisonment.U.S.

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Department of Health and Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments and governmental agencies.

The distribution of pharmaceutical drugs is subject to additional requirements and regulations, including extensive recordkeeping, licensing, storage and security requirements intended to prevent the unauthorized sale of such pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements may subject firms to legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, relabeling or repackaging, or refusal to allow a firm to enter into supply contracts, including government contracts. Any claim or action against us for violation of these laws, even if we successfully defends against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Prohibitions or restrictions on marketing, sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in statutes, regulations, or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling or packaging; (iii) the recall or discontinuation of our products; or (iv) additional recordkeeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Regulation Outside of the United States

In addition to regulations in the United States, we will be are subject to a variety of foreign regulations in other jurisdictions governing clinical trials and studies, commercial sales, and distribution of our products. Whether Most countries outside of the United States require that clinical trial applications be submitted to and approved by the local regulatory authority for each clinical study. In the EU, for example, an application must be submitted to the national competent authority and an independent ethics committee in each country in which we intend to conduct clinical trials, much like the FDA and IRB, respectively. Under the new CTR (EU) No 536/2014, which replaced the Clinical Trials Directive 2001/20/EC on January 31, 2022, a single application is now made through the Clinical Trials Information System, or CTIS, for clinical trial authorization in up to 30 EU/EEA countries at the same time and with a single set of documentation.

The assessment of applications for clinical trials is divided into two parts (Part I contains scientific and medicinal product documentation and Part II contains the national and patient-level documentation). Part I is assessed by a coordinated review by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted, or Member States concerned of a draft report prepared by a Reference Member State. Part II is assessed separately by each Member State concerned. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the Member State concerned, however overall related timelines are defined by the CTR. The new CTR also provides for simplified reporting procedures for clinical trial sponsors.

In addition, whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries outside the United States before we can commence clinical trials marketing of the product in those countries, if relevant, and market application approval by foreign countries or economic areas, such as the European Union, or EU, before we may market products in those countries or areas, countries. The approval process and requirements governing vary from country to country, so the conduct number and type of nonclinical, clinical, trials, product licensing, pricing, and reimbursement vary greatly from place to place, manufacturing studies needed may differ, and the time may be longer or shorter than that required for FDA approval.

Non-clinical Studies and Clinical Trials

Similarly to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical studies must be conducted in compliance with the principles of good laboratory practice, or GLP, as set forth in EU Directive 2004/10/EC. In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Conference on Harmonization, or ICH, guidelines on Good Clinical Practices, or GCP, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU countries, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. Unlike directives, the CTR is directly applicable in all EU member states without the need for member

states to further implement it into national law. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which contains a centralized EU portal and database.

While the Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state, to both the competent national health authority and an independent ethics committee, much like the FDA and IRB respectively, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed.

The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR.

Medicines used in clinical trials must be manufactured in accordance with Good Manufacturing Practice, or GMP. Other national and EU-wide regulatory requirements may also apply.

Marketing Authorization

In order to market our product candidates in the EU and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EU, medicinal product candidates can only be commercialized after obtaining a marketing authorization, or MA. To obtain regulatory approval of a product candidate our medicinal products under EU the EU's regulatory systems, system, we must are required to submit a MA marketing authorization application, or MAA. MAA, to be assessed in the centralized procedure. The process centralized procedure allows applicants to obtain a marketing authorization, or MA, that is valid throughout the EU, and the additional Member States of the European Economic Area (Iceland, Liechtenstein and Norway), or EEA. It is compulsory for doing this depends, among medicinal products manufactured using biotechnological processes, orphan medicinal products, advanced therapy medicinal products (gene-therapy, somatic cell-EU and which is intended for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, auto-immune and other things, immune dysfunctions, viral diseases or diabetes). The centralized procedure is optional for any other products containing new active substances not authorized in the EU or for products which constitute a significant therapeutic, scientific, or technical innovation or for which a centralized authorization is in the interests of patients at EU level. When a company wishes to place on the nature of the market a medicinal product. There are two types of MAs:

- "Centralized MAs" are issued by the European Commission through product that is eligible for the centralized procedure, based on it sends an application directly to the opinion of European Medicines Agency, or EMA, to be assessed by the Committee for Medicinal Products for Human Use, or CHMP. The CHMP is responsible for conducting the assessment of whether a medicine meets the required quality, safety, and efficacy requirements, and whether the product has a positive risk/benefit profile. Once the CHMP has completed its assessment, the CHMP will give a favorable or unfavorable opinion as to whether to grant the authorization. The time limit for the evaluation procedure is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the EMA).

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CHMP). The EMA then has fifteen days to forward its opinion to the European Commission, which will make a binding decision on the grant of an MA within 67 days of receipt of the CHMP opinion.

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as an orphan medicinal product if it is intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition that affects no more than five in 10,000 persons in the EU when the application is made. In addition, orphan designation can be granted if the product is intended for a life threatening, seriously debilitating, or serious and chronic condition in the EU and when, without incentives, it is unlikely that sales of the product in the EU would be sufficient to justify the necessary investment in its development. Orphan designation is only available if there is no other satisfactory method approved in the EU of diagnosing, preventing, or treating the applicable orphan condition, or if such a method exists, the proposed orphan medicinal product will be of significant benefit to patients affected by such condition, as defined in Regulation (EC) 847/2000.

Orphan designation provides opportunities for fee reductions, protocol assistance, and access to the centralized procedure. In addition, if a product which has orphan designation subsequently receives a centralized MA for the indication for which it has such designation, the product is entitled to orphan market exclusivity, which means the EMA may not approve any other application to market a similar medicinal product for the same indication for a period of ten years. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The exclusivity period may be reduced to six years if, at the end of the fifth year, it is shown that the designation criteria are valid through longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, an MA may be granted to a similar medicinal product for the same indication at any time if:

- the second applicant can establish that its product, although similar to the authorized product, is safer, more effective or otherwise clinically superior;

- the MA holder of the authorized product consents to a second orphan medicinal product application; or
- the MA holder of the authorized product cannot supply enough orphan medicinal product.

A pediatric investigation plan, or PIP, in the EU is aimed at ensuring that the necessary data are obtained to support the authorization of a medicine for children through studies in children. All applications for MAs for new medicines have to include the results of studies as described in an agreed PIP, unless the medicine is exempt because of a deferral or waiver. This requirement also applies when an MA holder wants to add a new indication, pharmaceutical form, or route of administration for a medicine that is already authorized and covered by intellectual property rights. Several rewards and incentives for the development of pediatric medicines for children are available in the EU. The centralized procedure Medicines authorized across the EU with the results of studies from a PIP included in the product information are eligible for an extension of their supplementary protection certificate, or SPC, by six months (provided an application for such extension is mandatory made at the same time as for the SPC application for certain types of products, such as (i) medicinal products derived from biotechnology processes, (ii) designated the product, or at any point up to five years before the SPC expires). This is the case even when the studies' results are negative. For orphan medicinal products, (iii) advanced therapy medicinal products (ATMPs) (such as gene therapy, somatic cell therapy and tissue engineered products) and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune, and viral diseases. The centralized procedure incentive is optional for products containing a new active substance not yet authorized in the EU; for products that constitute a significant therapeutic, scientific or technical innovation; or for products that are in the interest of public health in the EU. National MAs are issued by the competent authorities of the EU member states and only cover their respective territory, and are available for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in an EU member state, this national MA can be recognized in another member state through the mutual recognition procedure. If the product has not received a national MA in any member state at the time of application, it can be approved simultaneously in various member states through the decentralized procedure. Under the decentralized procedure, an identical dossier is submitted to the competent authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the reference member state.

- Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops.

Under the above described procedures, in order to grant the MA, the EMA or the competent authorities of the EU member states make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. MAs have an initial duration of five years. After these five years, the authorization may be renewed on the basis of a reevaluation of the risk-benefit balance.

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Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EU assess the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety, and efficacy.

Data and Marketing Exclusivity

As in the United States, it may be possible in foreign countries to obtain a period of market and/or data exclusivity that would have the effect of postponing the entry into the marketplace of a competitor's generic product. For example, in the EU new products authorized for marketing (i.e., reference products) generally receive eight years of data exclusivity and an additional two years of marketing exclusivity upon MA. If granted, market exclusivity. Scientific advice and protocol assistance at the data exclusivity period prevents generic EMA are free of charge for questions relating to the development of pediatric medicines.

In March 2016, the EMA launched an initiative, the Priority Medicines scheme, or the PRIME scheme, to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The PRIME scheme is intended to encourage development of products in areas of unmet medical need and biosimilar applicants provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. Products from relying on the preclinical small- and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial MA of the reference product in the EU. The overall ten-year market exclusivity period can be extended to a maximum of eleven years, if during the data exclusivity period (the first eight years of the ten year marketing exclusivity period) the MA holder obtains an authorization for one or more new therapeutic indications that are deemed to bring a significant clinical benefit compared to existing therapies. In Japan, our products medium-sized enterprises may be eligible for eight years of data exclusivity. There can be no assurance that a product candidate will qualify for such regulatory exclusivity, or that such exclusivity will prevent competitors from seeking approval solely earlier entry into the PRIME scheme than larger companies on the basis of their own studies.

Failure compelling non-clinical data and tolerability data from initial clinical trials. Many benefits accrue to comply sponsors of product candidates with EU PRIME designation, including but not limited to, early and member state laws that apply to proactive regulatory dialogue with the conduct of EMA, frequent discussions on clinical trials, manufacturing approval, MA of medicinal products trial designs and marketing of such products, both before other development program elements, and after grant potentially accelerated MAA assessment once a dossier has been submitted. Importantly, once a candidate medicine has been selected for the PRIME scheme, a dedicated contact and rapporteur from the CHMP or from the Committee for Advanced Therapies, or CAT, are appointed early in the PRIME scheme facilitating increased understanding of the MA, manufacturing product at EMA's committee level. An initial meeting with the CHMP/CAT rapporteur initiates these relationships and includes a team of pharmaceutical products, statutory health insurance, bribery multidisciplinary experts at the EMA to provide guidance on the overall development and anti-corruption regulatory strategies. PRIME eligibility does not change the standards for product approval, and there is no assurance that any such designation or with other applicable regulatory requirements may eligibility will result in administrative, civil expedited review or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

approval. The aforementioned EU rules are generally applicable in the European Economic Area, EEA. The United Kingdom left the EU on January 31, 2020.

The United Kingdom have concluded a trade and cooperation agreement, or EEA, TCA, which consists was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not provide for wholesale mutual recognition of United Kingdom and EU pharmaceutical regulations. At present, Great Britain has implemented EU legislation on the 27 EU member states plus Norway, Liechtenstein marketing, promotion and Iceland. sale of medicinal products

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through the Human Medicines Regulations 2012 (as amended). Except in respect of the new EU Clinical Trials Regulation, the regulatory regime in Great Britain therefore largely aligns with current EU medicines regulations, however it is possible that these regimes will diverge more significantly in future now that Great Britain's regulatory system is independent from the EU and the Regulatory Framework in the TCA does not provide for mutual recognition of United Kingdom

Since the end and EU pharmaceutical legislation. However, notwithstanding that there is no wholesale recognition of the Brexit transition period on January 1, 2021, Great Britain (England, Scotland and Wales) has not been subject to EU laws. However pharmaceutical legislation under the terms of the Ireland/Northern Ireland Protocol, Northern Ireland continues to follow EU law. The EU laws that have been transposed into United Kingdom, or UK, law through secondary legislation remain applicable in Great Britain. However, TCA, under the Retained EU Law (Revocation and Reform) Bill 2022, which is currently before the UK parliament, any retained EU law not expressly preserved and "assimilated" into domestic law or extended by ministerial regulations (to no later than 23 June 2026) will automatically expire and be revoked by December 31, 2023. In addition, new legislation such as the EU CTR is not applicable. The UK government has passed a new Medicines and Medical Devices Act 2021, framework which introduces delegated powers will be put in favor of the Secretary of State or an 'appropriate authority' to amend or supplement existing regulations in the area of medicinal products and medical devices. This allows new rules to be introduced in the future place by way of secondary legislation, which aims to allow flexibility in addressing regulatory gaps and future changes in the fields of human medicines, clinical trials and medical devices.

As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, is the UK's standalone United Kingdom's medicines and medical devices regulator. The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment and a rolling review procedure. All existing EU MAs for centrally authorized products were automatically converted or grandfathered into UK MAs, effective in Great Britain (only), free of charge on January 1, 2021, unless the MA holder chose to opt-out. After Brexit, companies established in the UK cannot use the centralized procedure and instead must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain an MA to commercialize products in the UK. For a period of three years regulator, from 1 January 2021, January 1, 2024, the MHRA may rely on a decision taken by the EU Commission will take into account decisions on the approval of a new (centralized procedure) MA MAs from the EMA (and certain other regulators) when determining considering an application for a Great Britain authorization; or use MA.

On February 27, 2023, the MHRA's decentralized or mutual recognition procedures which enable MAs approved United Kingdom government and the European Commission announced a political agreement in EU member states (or Iceland, Liechtenstein, Norway) principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework". This new framework fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the United Kingdom. In particular, the MHRA will be responsible for approving all medicinal products destined for the United Kingdom market (i.e., Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. A single United Kingdom-wide MA will be granted by the MHRA for all medicinal products to be granted sold in the United Kingdom, enabling products to be sold in a single pack and under a single authorization throughout the United Kingdom. On June 9, 2023, the MHRA announced that the medicines aspects of the Windsor Framework will apply after January 1, 2025.

There is now no pre-MA orphan designation in Great Britain. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding MAA. The criteria are essentially the same, but have been tailored for the Great Britain market, i.e., the prevalence of the condition in Great Britain (rather than the EU) must not be more than five in 10,000. Should an orphan designation be granted, the period of market exclusivity will be set from the date of first approval of the product in Great Britain or the EU, wherever is earliest.

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Coverage and reimbursement

Sales of any pharmaceutical product depend, in part, on Outside the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Significant uncertainty exists as to the coverage and reimbursement status of any newly approved product. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. One third-party payor's decision to cover a product does not ensure that other payors will also provide coverage for the product. As a result, the coverage determination process can require manufactures to provide scientific and clinical support for the use of a product to each payor separately, and can be a time-consuming process, with no assurance that United States, ensuring coverage and adequate reimbursement will payment for a product also involves challenges. Pricing of prescription pharmaceuticals is subject to government control in many countries. In some foreign countries, the proposed pricing for a drug must be applied consistently or obtained in the first instance. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement approved before it may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization.

In addition, third-party payors are increasingly reducing reimbursements for pharmaceutical products and services lawfully marketed. The U.S. government and state legislatures have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement, and requirements for substitution of generic products. Third-party payors are more and more challenging the prices charged, examining the medical necessity, and reviewing the cost effectiveness of pharmaceutical products, in addition governing drug pricing vary widely from country to questioning their safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. country. For example, the European Union EU provides options for its member states Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A member state Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products and may also compete with imported foreign products. Furthermore, there is There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow U.S. price structures and generally prices tend to be significantly lower.

Patients Rely on Insurance Coverage by Third-Party Payors (third-party payors include Medicare and Medicaid (government payors) and commercial insurance companies such as Blue Cross Blue Shield, Humana, Cigna, etc.) to Pay for Products

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations.

Additionally, the process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which products they will pay for and establish reimbursement levels. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication. Net prices for products may also be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that pharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be considered medically obtained. Even if

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coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

No Uniform Policy Exists for Coverage and Reimbursement in the U.S.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the CMS, an agency within the U.S. Department of Health and Human Services that implements the Medicare program. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree.

We currently expect that any drugs we develop may need to be administered under the supervision of a physician on an outpatient basis. Under currently applicable U.S. law, certain drugs that are not usually self-administered (such as most injectable drugs) may be eligible for coverage under the Medicare Part B program if:

- they are incident to a physician's services;
- they are reasonable and necessary for a specific indication, the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice; and
- they have been approved by the FDA and meet other requirements of the statute.

Pharmaceutical companies whose products are reimbursed under Medicare Part B must calculate and report certain price reporting metrics to the government, such as average sales price, and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for product candidates may be reduced by mandatory discounts or rebates required by government healthcare programs.

Further, during the COVID-19 pandemic, millions of individuals lost employer-based insurance coverage. It is unclear what effect, if any, the American Rescue Plan will be considered cost-effective by third-party payors, that an adequate level have on the number of reimbursement will be established even if coverage is available, or that the third-party payors' reimbursement policies will not covered individuals, which may adversely affect the our ability of manufacturers to sell products profitably.commercialize our products.

Other Healthcare Laws

Healthcare reformPharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business that may constrain the financial arrangements and relationships through which we research, as well as sell, market and distribute any products for which we obtain marketing authorization. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, and transparency laws and regulations related to drug pricing and payments and other transfers of value made to physicians and other healthcare providers. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations, exclusion from participation in federal and state healthcare programs and responsible individuals may be subject to imprisonment.

Affordable Care Act and Legislative Reform Measures

Payors, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs and those methods are not always specifically adapted for new technologies such as gene therapy and therapies addressing rare diseases such as those we are developing. In both the United States and certain foreign jurisdictions, there have been and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare health care system that could affect the pharmaceutical industry, impact our ability to sell our products profitably. In March particular, in 2010, the Affordable Care Act (ACA) ACA was signed into law, enacted, which, substantially changed the way healthcare is financed by both governmental and private insurers in the United States. The ACA contained a number of provisions of particular import to the pharmaceutical industry, including those governing enrollment in federal healthcare programs, reimbursement adjustments, and fraud and abuse changes. Additionally, the ACA increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; required the collection of rebates for drugs paid by Medicaid managed care organizations; imposed a nondeductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs; implemented among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; expanded increased the eligibility criteria minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for Medicaid programs; certain branded prescription drugs; created a new Patient-Centered Outcomes Research Institute Medicare Part D coverage gap discount program, in which manufacturers must agree to oversee, identify priorities in, offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and conducts provided incentives to programs that increase the federal government's comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.research.

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Since its enactment, there have been numerous judicial, executive administrative, and Congressional executive, challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order initiating a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare.

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Legislative In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On March 11, 2021, For example, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, or AMP, for single source and innovator multiple source drugs, beginning January 1, 2024. Moreover, there has recently been heightened governmental scrutiny over Further, the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries, Budget Control Act of 2011 and proposed and enacted subsequent legislation, designed, among other things, created measures for spending reductions by Congress that include aggregate reductions of Medicare payments to bring more transparency providers of 2% per fiscal year, which remain in effect through 2031. Due to product pricing, review the relationship between pricing Statutory Pay-As-You-

Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and manufacturer patient programs, subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation. The U.S. American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers and reform increased the statute of limitations period for the government program reimbursement methodologies for drug products. Most recently, on August 16, 2022, the to recover overpayments to providers from three to five years.

The Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, includes several provisions that may impact our business to varying degrees, including provisions that reduce the IRA requires manufacturers of out-of-pocket cap for Medicare Part D beneficiaries to \$2,000 starting in 2025; impose new manufacturer financial liability on certain drugs under Medicare Part D; allow the U.S. government to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under negotiate Medicare Part B and Medicare Part D price caps for certain high-cost drugs without generic competition; require companies to penalize pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the rebate rule that would limit the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price increases negotiation program, but only if they have one orphan designation and for which the only approved indication is for that outpace inflation (first due in 2023); and replaces disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the Part D coverage gap discount program with a new discounting program (beginning in 2025). The orphan drug exemption. Further, judicial challenges to the IRA permits may have an impact on the Secretary implementation of the Department IRA's provisions; and the overall effects of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated. on our business and the healthcare industry in general is not yet known.

Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and, in some cases, mechanisms to encourage importation from other countries and bulk purchasing. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference-pricing systems and publication of discounts and list prices.

Data privacy and security laws

Numerous state, federal and foreign laws, including consumer protection These laws and regulations govern may result in additional reductions in Medicare and other healthcare funding and otherwise affect the collection, dissemination, use, access prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Other U.S. Environmental, Health and Safety Laws and Regulations

We may be subject to confidentiality numerous environmental, health and security of personal information, including health-related information. In the United States, numerous federal and state safety laws and regulations, including data breach notification laws, health information privacy those governing laboratory procedures and security the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and consumer protection regulations.

We maintain workers' compensation insurance to cover costs and expenses we may incur due to injuries to our employees as well as insurance for environmental liability, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. may impair our research, development or production efforts. In addition, certain foreign failure to comply with these laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, substantial fines, penalties or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Cybersecurity

In the normal course of business, we may collect and store personal information and other sensitive information, including proprietary and confidential business information, trade secrets, intellectual property, information regarding trial participants in connection with clinical trials, sensitive third-party information and employee information. To protect this information, our existing cybersecurity policies require monitoring and detection programs, network security precautions, encryption of critical data, and security assessment of vendors. We maintain various protections designed to safeguard against cyberattacks. We have established and test our disaster recovery plan and we protect against business interruption by backing up our major systems. In addition, we scan our environment for any vulnerabilities, perform penetration testing and engage third parties to assess effectiveness of our data security practices. A third party security consultant conducts regular network security reviews, scans and audits.

Our cybersecurity program is comprised of Company employees and a third-party cybersecurity vendor, all of whom are highly skilled cybersecurity professionals. Our program incorporates industry-standard frameworks, policies and practices designed to protect the privacy and security of our sensitive information.

Despite the implementation of our cybersecurity program, our security measures cannot guarantee that a significant cyberattack will not occur. A successful attack on our information technology systems could have significant consequences to the business. While we devote resources to our security measures to protect our systems and information, these measures cannot provide absolute security. See "Risk Factors – risks related to our employees, managing our growth and our operations" for additional information about the risks to our business associated with a breach or compromise to our information technology systems.

Environmental, Social, and Governance Initiatives

Corporate sustainability and environmental responsibility

We understand the importance of reducing our environmental impact. We are proud to be headquartered in a LEED certified building, a globally recognized symbol of sustainability achievement and leadership. We continue to promote sustainability within our office by limiting single-use plastic and implementing compost and recycling programs. Our current hybrid work model allows employees to work remotely for a portion of the week, decreasing the emissions associated with employees commuting to the office.

Diversity & Inclusion

We are committed to creating and maintaining a workplace free from discrimination or harassment on the basis of color, race, sex, national origin, ethnicity, religion, age, disability, sexual orientation, gender identification or expression, or any other status protected by applicable law. Our management team and employees are expected to exhibit and promote honest, ethical and respectful conduct in the workplace. All of our employees must adhere to a code of conduct that sets standards for appropriate behavior and are required to attend training upon hire and at our request to help prevent, identify, report and stop any type of discrimination and harassment. Ongoing acknowledgment of our anti-harassment policy is required on an annual basis. Our recruitment, hiring, development, training, compensation and advancement at our company is based on qualifications, performance, skills and experience without regard to gender, race and ethnicity. Our Diversity, Equity & Inclusion (DEI) Committee is an employee-led group that works to raise awareness for DEI initiatives and identify ways we can continue to promote inclusion within our corporate culture. Although we are a smaller reporting company, our Board of Directors meets the requirements under NASDAQ's Board Diversity Rule for accelerated and large-accelerated filers with two diverse directors.

sanctions.

Employees and Human Capital Resources

As of February 1, 2023 December 31, 2023, we had 48 101 full-time employees, including 46 full-time employees. Women represent approximately 46% of our 34 who hold Ph.D. degrees, and one part-time employee; 74 employees are engaged in research and 29% of our senior development and 27 employees are engaged in management level/leadership roles. Thirty-eight percent of our employees have a Ph.D. or doctorate. From time to time, we also retain independent contractors to support our organization. general and administrative activities. None of our employees are subject to a collective bargaining agreement or represented by a trade or labor union or covered by collective bargaining agreements, and we believe union. We consider our relationship with our employees is to be good. We also employ consultants from time to time, including to assist with Merger integration efforts.

Our human capital objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

We strive to provide pay, comprehensive benefits and services that help meet the varying needs of our employees. Our total rewards package includes competitive pay; comprehensive healthcare benefits package for employees, with family member healthcare benefits covered at 90%; a health savings account with company contribution; unlimited paid time off and paid holidays; family medical leave; and flexible work schedules. In addition, we offer every full-time employee, both exempt and non-exempt, the benefit of equity ownership in the company through stock option grants, restricted stock units, and our employee stock purchase plan. We also sponsor a 401(k) plan with a 5% match. 45

We focus on attracting, retaining, and cultivating talented individuals. We emphasize employee development and training by providing access to a wide range of online and instructor led development and continual learning programs. Employees are encouraged to attend scientific, clinical and technological meetings and conferences and have access to broad resources they need to be successful.

On February 13, 2023, we announced a reduction in force of approximately 55% of our workforce, which will take place in phases and is expected to be completed by April 30, 2023.

Safety

The safety, health and wellness of our employees is a top priority. In response to public health emergencies, including COVID-19, we have implemented safety protocols including a flexible hybrid work schedule for non-lab based employees, optional wearing of masks, regular cleaning procedures and readily available hand sanitizer. These protocols are designed to comply with health and safety standards as required by federal, state and local government agencies, taking into consideration guidelines of the Centers for Disease Control and Prevention and other public health authorities.

Our Corporate Information

We were incorporated under the laws of the state of Delaware in November 2014. Our principal executive offices are located at 75 Hayden Avenue, Suite 300, Lexington, Massachusetts 02421 and our telephone number is (781) 315-4600. Our corporate website address is www.frequencytx.com. The information contained in, or accessible through, our website is not incorporated by reference into this Annual Report and you should not consider information on our website to be a part of this Annual Report. We have included our website address in this Annual Report solely as an inactive textual reference.

Where you can find more information

Item 1A. Risk Factors.

Our future operating results could differ materially from You should consider carefully the results risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K due to and in our other filings with the Securities and Exchange Commission, or SEC. We operate in a dynamic and rapidly changing industry that involves numerous risks and uncertainties. The risks and uncertainties described below. You should below are not the only ones we face. Other risks and uncertainties, including those that we do not currently consider carefully the following information about risks below in evaluating material, may impair our business. If any of the following risks discussed below actually occur, our business, financial conditions, condition, operating results of operations and future growth prospects would likely or cash flows could be materially and adversely affected. Additional This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. In these circumstances, the market price of our common stock would likely decline. In addition, we cannot assure investors that our assumptions and expectations will prove to be correct. Important factors could cause our uncertainties. Our actual results to could differ materially from those indicated or implied by forward-looking statements. See "Forward Looking Statements" for a discussion of some of the anticipated in these forward-looking statements that are qualified by these risk factors. Factors that could cause or contribute to such differences include those as a result of certain factors, discussed below, including the risks we face as described below and elsewhere in this Annual Report on Form 10-K. See "Cautionary Statement Regarding Forward Looking Statements."

Risks related Related to our financial position and need for additional capitalOur Business

Risks Related to Our Financial Position and Need for Capital

We have incurred significant losses since inception and anticipate that we will continue inception. We expect to incur losses for the foreseeable future. We are not currently profitable, future and we may never achieve or sustain maintain profitability. If we are unable to achieve or sustain profitability, the market value of our common stock will likely decline.

We are a clinical-stage biotechnology company with a limited operating history. As a result, Since inception, we are not profitable and have incurred significant losses since our formation. We had operating losses. Our net losses of \$81.6 million loss was \$81.2 million and \$84.7 million \$58.0 million for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively. As of December 31, 2022 December 31, 2023, we had an accumulated deficit of \$261.7 million \$183.0 million. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to gain regulatory approval and become commercially viable. We have not commercialized any products and have never generated revenue from the commercialization of any product. To date, we have devoted most financed our operations primarily through private placements of our financial resources preferred stock and more recently, common stock in the pre-closing financing that closed immediately prior to licensing technologies and the Merger. Substantially all of our losses have resulted from expenses incurred in connection with our research and development including and from general and administrative costs associated with our preclinical platform development activities and clinical trials.

operations. We expect to continue to incur significant additional expenses, increasing operating losses, and negative operating cash flows for the next several years, at least, as foreseeable future. The net losses we advance a potential therapeutic candidate for multiple sclerosis, or MS, and any other product candidate through clinical development, complete clinical trials, seek regulatory approval and commercialize an MS therapeutic or any other product candidate, if approved. The costs of advancing product candidates into each clinical phase tend incur may fluctuate significantly from quarter to increase substantially over the duration of the clinical development process. Therefore, the total costs to advance any product candidate to marketing approval in even a single jurisdiction are substantial. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased quarter. We anticipate that our expenses or when, or if, we will be able to begin generating revenue from the commercialization of any product candidates or achieve or maintain profitability. Our expenses will also increase substantially if and as we:

- continue to develop current research programs and commence clinical trials preclinical development of our remyelination program in MS;
- expand our development programs based on our progenitor cell activation, or PCA, approach;
- continue to develop our PCA approach; any product candidates we may identify;
- seek regulatory approvals for an MS therapeutic to identify additional research programs and any other product candidates;
- secure a commercial manufacturing source initiate preclinical studies and supply chain capacity sufficient to produce commercial quantities of clinical trials for any product candidate for which candidates we obtain regulatory approval; may identify;
- further develop Oligonucleotide Promoted Editing of RNA, or OPERA, our RNA editing platform;
- maintain, expand, enforce, defend and protect our intellectual property portfolio and provide reimbursement of third-party expenses related to our intellectual property portfolio;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- develop, maintain and enhance a sustainable, scalable, reproducible and transferable manufacturing process for the product candidates we may develop;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize an MS therapeutic, if approved, and for any other product candidates therapies which we may obtain marketing approval;
- maintain, expand, hire additional research and protect development personnel;

- hire clinical and commercial personnel;
- add operational, financial and management information systems and personnel, including personnel to support our intellectual property portfolio; and product development;
- acquire or in-license other product candidates, intellectual property and technologies;
- establish and maintain collaborations;
- should we decide to do so, build and maintain commercial-scale current Good Manufacturing Practices, or technologies, cGMP, manufacturing facility;

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- experience any delays or interruptions due to global pandemics, such as the recent COVID-19 endemic, or other events unrelated to our business such as the Russia invasion of Ukraine or Israeli-Hamas conflict that could result in delays in preclinical testing and clinical trials or interruptions in the supply chain; and
- operate as a public company.

Furthermore, our ability We have not initiated clinical development of any potential product candidate and expect that it will be many years, if ever, before we have a RNA editing therapy ready for commercialization. To become and remain profitable, we must develop and, either directly or through collaborators, eventually commercialize a therapy or therapies with market potential. This will require us to successfully develop, commercialize and license any be successful in a range of challenging activities, including identifying product candidates, completing preclinical studies and clinical trials of product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those therapies for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in these activities and, even if we do, may never generate product revenue is subject revenues that are significant or large enough to substantial additional achieve profitability.

We have transitioned from discovery, research and development to early preclinical development for our development candidate, KRRO-110. Because of the numerous risks and uncertainties as described under “—Risks related to development, clinical testing, manufacturing, and regulatory approval” and “—Risks related to commercialization.” As a result, we expect to continue to incur net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders’ equity and working capital. The amount of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If associated with developing oligonucleotide product candidates, we are unable to develop and commercialize one predict the extent of any future losses or more product candidates, either alone or through collaborations, or if revenues from any product that receives marketing approval are insufficient, when we will not achieve

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profitability. Even become profitable, if we successfully commercialize an MS therapeutic or any other product candidates, we may continue to incur substantial research and development and other expenses to identify and develop other product candidates. Even if at all. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or meet outside expectations for our profitability. If we are unable annual basis. Our failure to achieve or sustain profitability or to meet outside expectations for our profitability, become and remain profitable would decrease the value of our common stock will be materially adversely affected. company and could impair our ability to raise capital, maintain our research and development efforts, expand business or continue our operations. A decline in our value could also cause you to lose all or part of your investment.

We will require additional capital to fund our operations, have never generated revenue from product sales and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of an MS therapeutic or explore additional product candidates. never become profitable.

We expect Our ability to spend substantial amounts generate revenue from product sales and achieve profitability depends on our ability, alone or with collaborative partners, to successfully complete the development of, seek and obtain the regulatory approvals necessary to commercialize, product candidates we may identify for development. We do not anticipate generating revenues from product sales for many years, if ever. Our ability to generate future revenues from product sales depends heavily on our, or our collaborators’, ability to successfully:

- identify product candidates and if approved, commercialize an MS therapeutic successfully complete research and any other product candidates. These expenditures include and will include, as the case may be, preclinical development costs and costs related to trials we conduct to support the development of an MS therapeutic suc product candidates;
- seek and obtain regulatory and marketing approvals for any other product candidates, candidates for which we complete clinical trials;
- We will launch and commercialize any product candidates for which we may acquire through equity offerings, debt financings, obtain regulatory and marketing app require establishing a sales force, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements infrastructure, additional Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have alterns capital to collaborating with a negative effect on our financial condition and our ability to pursue our business strategy. In addition, attempting to secure additional fin enable us the time and attention of our management from day-to-day activities and harm our development efforts.
- to develop Based upon our current operating plan, and as a result of the realignment of the Company to focus on the MS program, including cost saving mea reduction in force during the first half of 2023, we believe that our existing cash, cash equivalents, and marketable securities of \$83.1 million will enable us

an MS operating expenses and capital expenditure requirements into 2025. This estimate and our expectation regarding the sufficiency of our current financial resources to advance the development of an MS therapeutic and any other product candidates are based on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect, or our planned Phase 1 study in our program for remyelination in MS may be more expensive, time consuming to design or implement than we currently anticipate. Changing circumstances, including any unanticipated expenses, could cause us to consume capital resources more than we currently anticipate, and we may need to spend more than currently expected because of circumstances beyond our control. Because the length and scope of activities associated with successful development of an MS therapeutic or any product candidate we may develop is highly uncertain, we are unable to estimate the funds we will require for development and any marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on a number of factors, including, but not limited to:

- the initiation, progress, timing, costs and results of our clinical trials through all phases of development, including the planned Phase 1 study and the development of any other product candidates including any unforeseen costs we may incur as a result of the COVID-19 global pandemic and other causes; partner;
- qualify for adequate coverage and reimbursement by government and third-party payors for any product candidates for which we may obtain marketing approval;
- establish and maintain supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, product to support clinical development and the outcome, timing market demand for any product candidates for which we obtain regulatory and commercial approval;
- develop, maintain and enhance a sustainable, scalable, reproducible and transferable manufacturing process for the product candidates we may develop;
- address competing technological and market developments;
- negotiate favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations in connection with such arrangements;
- receive market acceptance by physicians, patients, healthcare payors, and others in the medical community;
- maintain, protect, enforce, defend and expand our portfolio of meeting regulatory requirements established intellectual property and other proprietary rights, including patents, trade secrets and know-how;
- defend against third party intellectual property claims of infringement, misappropriation or other violation; and
- attract top talent and retain qualified personnel.

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Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration, or the FDA, and other comparable regulatory authorities, including any clinical trials required by the FDA European Medicines Agency, or the EMA, or other comparable foreign regulatory authorities.

the willingness of the FDA and other comparable foreign regulatory authorities to accept perform clinical and other studies in addition to those that we currently anticipate. Even if one or more of the product candidates we may develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Additionally, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives. Even if we are able to generate revenues from the sale of any approved product candidates, we may not become profitable and may need to obtain additional funding to continue operations.

We will need substantial additional funding. If we are unable to raise capital when needed, we will be forced to delay, reduce, eliminate or prioritize among clinical trial designs, research and development programs or future commercialization efforts.

We expect our expenses to continue to increase in connection with our ongoing activities, particularly as well as data from our planned we identify, continue the research and development of, initiate preclinical studies and clinical trials of, and preclinical studies, as the basis seek marketing approval for, review product candidates. Because we have limited financial and approval managerial resources, we have prioritized our research programs and lead optimization efforts in specific indications and many potential options. Specifically, our initial development programs target liver and central nervous systems indications, amongst others. As a result of an MS therapeutic and any this prioritization, we may forego or delay pursuit of opportunities with other product candidates;

candidates or for other indications that later prove to have greater clinical or commercial potential and we may need to reprioritize our focus in the cost future. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable therapies.

In addition, if we obtain marketing approval for any product candidates we may develop, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of filing, prosecuting, defending, and enforcing our patent claims and other intellectual property rights;

the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us;

the effect of competing technological and market developments;

- the cost and timing of completion of commercial-scale manufacturing activities;
- the a collaborator. Furthermore, we expect to incur additional costs of associated with operating as a public company;
- the extent company. Accordingly, we will need to which obtain substantial additional funding in connection with our continuing operations. If we in-license are unable to capital when needed or acquire other on attractive terms, we would be forced to delay, reduce or eliminate our research and product candidates development program technologies;
- the cost of establishing sales, marketing and distribution capabilities for our product candidates, if approved; and
- the initiation, progress, and timing of our future commercialization of an MS therapeutic, if approved, or our other product candidates.

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efforts.

Depending As of December 31, 2023, our cash and cash equivalents were \$166.1 million, excluding restricted cash, or \$173.1 million, including restricted cash. We believe our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements through several value-creating milestones and into 2026. However, our operating plan may change as a result of factors currently unknown, and expectations regarding our cash runway and ability to reach data inflection points are based on our business performance, the economic climate and market conditions, numerous assumptions that may prove to be untrue. As a result, we may be unable required to raise capital sooner than anticipated and our exposure to certain contingent liabilities and contractual obligations may be greater than anticipated. Our future capital requirements will depend on many other factors, including those discussed in the risk factor entitled "We have incurred significant losses since inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability."

Any additional funds through any sources. Market volatility resulting fundraising efforts may divert our management from the COVID-19 global pandemic, the conflict in Ukraine, the escalation of tensions between China and Taiwan, global supply chain issues, and increased inflation could also their day-to-day activities, which may adversely impact affect our ability to access develop and commercialize any product candidates we may develop. We cannot be certain that additional funding will be available on acceptable terms or at all. We have no committed source of additional capital as and, when needed. If if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of an MS therapeutic or any other product candidates or potentially discontinue operations, other research and development initiatives. We could be required to seek collaborators for potential product candidates earlier than we would otherwise plan or on terms that are less favorable than might otherwise be available. We could also be required to relinquish or license our rights to product candidates on unfavorable terms in certain markets where we otherwise would seek to pursue development or commercialization ourselves.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates we may develop.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our capital needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends and possibly other restrictions. In addition, if we raise funds through additional license and collaboration agreements, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, technologies, future revenue streams, research programs or product candidates we may develop, or we may have to grant licenses on terms that may not be favorable.

We have a limited 48

Our operating history and no history of commercializing pharmaceutical products, which may make it difficult for you to evaluate the prospects for success of our business to date and to assess our future viability.

We were established Our business has now become that of Legacy Korro, an early-stage company founded in September 2018 and began which commenced operations in 2014. Our October 2019. Prior to the Merger, Legacy Korro's operations to date have been (which are now ours) were limited to financing organizing and staffing, our company, licensing technologies, business planning, raising capital, acquiring and developing our PCA approach, developing platform and conducting technology and identifying and beginning to advance preclinical testing of potential product candidates. All of our current programs are still in the research or preclinical stage of development and clinical studies their risk of FX-322 for the treatment of SNHL, and developing a pipeline of preclinical and research programs, including FX-345 and our remyelination program in MS. failure is high. We have not yet demonstrated the an ability to initiate or successfully complete a any clinical trials, including large-scale, pivotal clinical trial, trials, obtain marketing approval, approvals, manufacture a commercial-scale product, or therapy, arrange for a third party to do so on our behalf or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions Typically, it takes about 10 to 15 years to develop a new therapy from the time it is discovered to when it is available for treating patients.

Legacy Korro's limited operating history, particularly in light of the rapidly evolving gene editing field, may make it difficult to evaluate our technology and industry and predict our future performance. Accordingly, any assessment of our future success or viability may be subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by very early-stage companies in rapidly evolving fields. If we do not perform as well as we expect, our business may be adversely affected. If we do not successfully develop and commercialize pharmaceutical products, our business will suffer.

In addition, as a new business, with a limited operating history, we may encounter other unforeseen expenses, difficulties, complications, delays, and other known and unknown challenges. Our FX-322 Phase 2b results (FX-322-208), for example, showed no statistically significant difference at day 90 between those administered FX-322 versus those receiving placebo in the proportion of individuals that demonstrated an improvement in speech perception. We will eventually need to transition from a company with a research focus to a company capable of supporting commercial activities. We may not be successful in such a transition and, as a result, our business may be adversely affected.

As we continue to build our business, we expect our financial condition and operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, the results of any quarterly or annual period are not necessarily indicative of future operating performance.

Our ability to use our net operating loss, or NOL, carryforwards to offset future taxable income, or and certain other tax credit carryforwards to offset future income tax liabilities, attributes may be subject to certain limitations.

Since our inception, we have incurred losses and we may never achieve profitability. As of December 31, 2022, we had net operating loss carryforwards, or federal and state NOLs of \$174.1 million for federal income tax purposes and \$302.5 million and \$141.3 million for state income tax purposes, which may be available to offset \$266.3 million, respectively. Under current law, our future taxable income, if any. Our NOLs expire in various amounts through 2042, provided that federal NOLs generated in taxable years ending after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80% of our taxable income annually for tax years beginning after December 31, 2018. Federal NOLs generated in taxable years ending on or prior to December 31, 2017 will, however, have a 20-year carryforward period, but are not be subject to expiration. We have federal NOLs of \$22.4 million that are subject to expiration between 2036 and 2037 and have \$280.1 million of federal NOLs that do not expire. Our state NOLs expire at various dates from 2035 through 2043. As of December 31, 2022, we also had federal research and development tax credit carryforwards of \$15.6 million that expire at various dates from 2036 through 2043. In addition, as of December 31, 2023, we had state research and development and other tax credit carryforwards of approximately \$8.2 million and \$3.6 million, respectively, available to reduce future income tax liabilities. Our tax credit carryforwards \$8.7 million that expire at various dates from 2032 through 2042. These NOLs 2038 and state investment tax credit carryforwards could of \$0.2 million that expire unused, to the extent subject to expiration, and be unavailable to offset future taxable income or income tax liabilities, as applicable. In addition, in general, under at various dates from 2024 through 2025.

Under Sections 382 and 383 of the U.S. Internal Revenue Code, of 1986, as amended, or the Code, if a corporation that undergoes an "ownership change" is subject to limitations on its change," generally defined as one or more shareholders or groups of shareholders who own at least 5% of the corporation's equity increasing their equity ownership in the aggregate by more than 50 percentage points (by value) over a rolling three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax credit carryforwards attributes (such as research and development tax credits) to offset future taxable income. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one its post-change income or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. taxes may be limited. Similar rules may apply under state tax laws. We believe we Our prior equity offerings and other changes in our stock ownership may have experienced resulted in such ownership changes in 2017 and 2019 and the past. We have not conducted a formal study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception. In addition, we may experience ownership changes in the future as a result of future transactions securities offering or subsequent shifts in our stock ownership, some of which may be outside of our control. As a result In particular, if the Merger or the Pre-Closing Financing constitutes an ownership change within the meaning of the ownership changes in 2017 and 2019, \$0.01 million and \$0.04 million of NOL carryforwards are limited under Section 382 of the Code. If Code, we undergo additional ownership changes, could lose or otherwise be substantially limited in our ability to use our NOLs and tax credit carryforwards carryforwards. As a result, if we earn net taxable income in the future, our ability to use our pre-change NOLs or other pre-change tax attributes to offset U.S. federal taxable income or income taxes may be subject to limitations, which could potentially result in increased future tax liability to us. There is a risk that due to changes under the tax law, regulatory changes or other unforeseen reasons, our existing NOLs or business tax credits could expire or otherwise be further limited, unavailable to offset future income tax liabilities. At the state level, there may also be periods during which the use of NOLs or business tax credits is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed by us. For these reasons, we may not be able to use realize a material portion tax benefit from the use of our NOLs or tax credit carryforwards, credits, even if we attain profitability. Furthermore,

Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition.

The rules dealing with U.S. federal, NOLs generated state and local income taxation are constantly under review by persons involved in taxable the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our business and financial condition. In recent years, beginning after December 31, 2017 may be carried forward indefinitely but may only be used many such changes have been made and changes are likely to offset 80% of our taxable income continue to occur in years beginning after December 31, 2020, which may require us to pay federal income taxes the future. We cannot predict whether, when, in future years despite generating federal NOLs in prior years. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future tax benefit of such assets. what form or with

what effective dates, tax laws, regulations and rulings may be enacted, promulgated or decided or whether they could increase our tax liability or require changes in the manner in which we operate in order to minimize increases in our tax liability.

Risks related Related to development, clinical testing, manufacturing, Discovery, Development and regulatory approvalCommercialization

The gene editing field and RNA editing in particular is relatively new and is evolving rapidly. We are very early in our development efforts and may not be successful in identifying and developing product candidates. It will be many years before we or our collaborators commercialize a product candidate or generate any revenues, if ever. Additionally, other gene editing technologies may be discovered that provide significant advantages over RNA editing, which could materially harm our business.

We are heavily dependent on the The success of our MS Program, which is still under development, and if an MS therapeutic does not receive regulatory approval or is not successfully commercialized, our business will be materially adversely harmed.

To date, we have invested a significant portion of our efforts and financial resources in the development of FX-322 for the treatment of SNHL. We recently discontinued our FX-322 and FX-345 development programs following the results of our FX-322 Phase 2b study which showed no statistically significant difference at day 90 between those administered FX-322 versus those receiving placebo in the proportion of individuals that demonstrated an improvement in speech perception. Our future success is substantially dependent on depends primarily upon our ability to successfully complete identify, develop and commercialize product candidates. We are very early in our development efforts and have focused our research and development efforts to date on developing OPERA, our RNA editing platform, and identifying our initial targeted disease indications. Although we believe we can demonstrate many of the key advantages of RNA editing, because we are very early in our development efforts, we are not yet certain of the results we may achieve, which may be important for obtain registration and commercialization of our products. Such uncertainties include, but are not limited to, the level of editing efficiency needed in a target tissue type to achieve a clinical benefit, and associated safety of our edits in humans. We have also not yet shown that preclinical editing activity can result in clinically important effects, nor that the data generated by our preclinical studies can translate into positive results in clinical trials.

All of our product development programs are still in the research or preclinical stage of development. Our research methodology may be unsuccessful in identifying product candidates, our product candidates may be shown to have harmful side effects in preclinical *in vitro* experiments or animal model studies, they may not show promising signals of therapeutic effect in such experiments or studies or they may have other characteristics that may make the product candidates impractical to manufacture, unmarketable, or unlikely to receive marketing approval.

The pharmacological properties ascribed to the product candidates we are testing in preclinical studies may not be positively demonstrated in clinical trials in patients, and they may interact with human biological systems in unforeseen, ineffective or harmful ways. If our product candidates prove to be ineffective, unsafe or commercially unviable, OPERA and our pipeline would have little, if any, value, which would substantially harm our business, financial condition, results of operations and prospects. In addition, our approach, which focuses on using oligonucleotides for drug development, as opposed to multiple or other, more advanced proven technologies, and new products and technologies that may enter the market, may expose us to additional financial risks and make it more difficult to raise additional capital if we are not successful in developing one or more product candidates that receive regulatory approval approval. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and successfully commercialize an MS therapeutic, eventual commercialization of any product candidates we may discover, which may never occur. We currently have generate no products that are approved for commercial sale revenue from sales of any product, and we may never be able to develop or commercialize a marketable product. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to our MS program, which will require additional clinical development, management of clinical and manufacturing activities, regulatory approval, establishing commercial scale manufacturing, and significant sales, marketing, and distribution efforts before we can generate any revenues from any commercial sales. We cannot be certain that we will be able to successfully complete any of these activities or that, even if it receives regulatory approval, a remyelinating therapeutic will be as effective as anticipated at treating MS.

The research, testing, manufacturing, labeling, approval, sale, packaging, marketing, In addition, although we believe OPERA, our RNA editing platform, will position us to expand our portfolio of product candidates beyond the initial product candidates we may develop, we have not yet successfully developed any product candidate and distribution of drug products are our ability to expand our portfolio may never materialize.

Commencing clinical trials in the United States is also subject to extensive regulation acceptance by the FDA of any future investigational new drug applications, or INDs, and comparable finalization of trial designs based on discussions with the FDA and other regulatory authorities. Even after we receive and incorporate guidance from these regulatory authorities, in other countries. We are not permitted to market an MS therapeutic until we receive regulatory approval from the FDA or comparable regulatory authorities in other countries, and we may never receive such regulatory approval. As a result, our financial position will be materially adversely affected, and we may not be able to generate sufficient revenue to continue our business.

We utilize our PCA approach to develop product candidates that are designed to activate progenitor cells, which is a new approach to therapeutic intervention and, as a result, successful development, approval, and commercialization of any product candidates, including an MS therapeutic, is uncertain.

We utilize our PCA approach to develop product candidates, including in our MS Program. Our PCA approach is designed to identify pathways to activate progenitor cells already present in the body to treat conditions or diseases through cellular regeneration. We have not, nor to our knowledge has any other company, received regulatory approval

utilizing this mechanism of cellular regeneration. Given the novelty of our approach, we could encounter a longer than expected regulatory review process, increased development costs, or unexpected delays in, or even prevention of, the regulatory approval and commercialization of our product candidates, and we cannot be certain that our approach will lead to the development of any approvable or marketable products.

Clinical trials are expensive, time consuming, and difficult to design and implement, and involve an uncertain outcome. The results of preclinical studies and early clinical trials are not always predictive of future results. Any product candidate that we advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and completed clinical trials are not necessarily predictive of future results, and any product candidates we develop may not be further developed or may have additional unfavorable results in later studies or trials. Clinical trial failure may result from a multitude of factors, including, but not limited to, flaws in study design, dose selection, placebo effect, subject enrollment criteria, selection of subjects based on subject misrepresentations, and failure to demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at any stage of testing. Several companies in the pharmaceutical industry have suffered setbacks in the advancement of their drug candidates into later-stage clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding favorable results in earlier preclinical studies or clinical trials. Our FX-322 Phase 2b results (FX-322-208), for example, showed no statistically significant difference at day 90 between those administered FX-322 versus those receiving placebo in the proportion of individuals that demonstrated an improvement in speech perception. Based upon negative or inconclusive results or a need for additional information, we may decide, or regulatory authorities may require us, to conduct additional clinical trials or preclinical studies.

We may experience delays in initiating and completing any clinical trials that we intend to conduct, and we do not know whether our clinical trials will begin on time, need to be redesigned, enroll subjects on time, or be completed on

schedule, or at all. For example, a number of clinical trial sites for our completed Phase 2a clinical trial of FX-322 (FX-322-202) temporarily halted subject enrollment during the first and second quarter of 2020 in response to the COVID-19 pandemic. Enrollment in other planned clinical trials could be adversely affected by the pandemic. Clinical trials can be delayed for a variety of reasons, including delays related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies;
- obtaining regulatory approval to commence a trial;
- reaching an agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining Institutional Review Board, or IRB, approval at each site within the United States, or Independent Ethics Committee, or IEC, approval at sites outside the United States;
- business interruptions resulting from the COVID-19 pandemic;
- recruiting suitable subjects to participate in a trial in a timely manner and in sufficient numbers;
- having subjects complete a trial or return for post-treatment follow-up;
- imposition of a clinical hold by regulatory authorities, including as a result of unforeseen safety issues or side effects or failure of trial sites or investigators to adhere to regulatory requirements or follow trial protocols;
- clinical sites deviating from the trial protocol or dropping out of a trial;
- addressing subject safety concerns that arise during a trial;
- adding a sufficient number of clinical trial sites; or
- manufacturing sufficient quantities of a product candidate for use in clinical trials.

We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs or IECs of the institutions in which such trials are being conducted, the FDA or other regulatory authorities or recommended for termination by a Data and Safety Monitoring Board, or DSMB, for such trial. Such authorities may impose a suspension or termination or recommend an alteration due to a number of factors, including failure to conduct the trial in accordance with regulatory requirements or change their position on the acceptability of our trial designs or any clinical protocols, inspection of the endpoints selected, which may require us to complete additional studies or trials or impose stricter approval conditions than we expect. There are equivalent processes and risks applicable to clinical trial operations applications, or trial site by CTAs, in other countries, including in Europe, the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial. UK and Australia.

Furthermore, Even if we rely on CROs and clinical trial sites to ensure complete the proper and timely conduct of our necessary clinical trials, and, while we have agreements governing their committed activities, we have limited influence over their actual performance, as described in the section titled “—Risks related to our dependence on third parties.”

Our MS Program is still in development and will require the successful completion of several trials before we are prepared to submit an NDA for regulatory approval by the FDA.

If we experience delays in the commencement or completion of any clinical trials, cannot predict when, or if, we terminate a clinical trial prior to completion, the commercial prospects of any product candidate we develop could be harmed, and our ability to generate revenues may be delayed. In addition, any delays in our clinical trials could increase our costs, slow the development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may materially harm

our business, financial condition, and results of operations. In addition, many of the factors that may cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming, and inherently unpredictable, and if we are ultimately unable to will obtain regulatory approval for an MS therapeutic, or any other product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during a product candidate's clinical development and may vary among

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jurisdictions. The approval process may also be delayed by changes in government regulation, the impact of the COVID-19 pandemic, future legislation or administrative action. We have not obtained regulatory approval for any product candidate and it is possible that we will never obtain regulatory approval for any product candidate. We are not permitted to market any of our commercialize our product candidates in the United States until we receive approval of an NDA from the FDA.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authority, that such product candidates are safe and effective for their intended uses. In addition, data obtained from preclinical trials and clinical trials are susceptible to varying interpretations, and regulatory authorities may not interpret our data as favorably as we do, which may further delay, limit, or prevent development efforts, clinical trials, or marketing approval. Furthermore, as more competing drug candidates within a class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other comparable regulatory authorities.

The FDA or any foreign regulatory authority can delay, limit, or deny approval of an MS therapeutic that we develop or require us to conduct additional preclinical or clinical testing or abandon a program for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates, or other products containing an active ingredient in our product candidates;
- negative or ambiguous results from our clinical trials or results that may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical trials;
- the FDA's or the applicable foreign regulatory authority's disagreement regarding the formulation, the labeling, and/or the specifications of our product candidates;
- the FDA or comparable foreign regulatory authorities may fail to approve or find deficiencies with the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; and
- significant regulatory GxP non-compliance or data integrity findings from FDA Bioresearch Monitoring inspections or pre-approval inspections inclusive of clinical investigator sites, contracted partners and their company's quality management system and execution thereof.

Of the large number of drugs in development, only a small percentage successfully complete the regulatory approval processes and are commercialized. This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations, and prospects.

In addition, the FDA or the applicable foreign regulatory authority also may approve a product candidate for a more limited indication or patient population than we originally requested, and the FDA or applicable foreign regulatory authority may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing circumstances could materially harm the commercial prospects for our product candidates and our business.

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Enrollment and retention of individuals in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of subjects who remain in the study until its conclusion. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of subjects to complete any of our clinical trials, and even once

enrolled, we may be unable to retain a sufficient number of subjects to complete any of our trials.

Subject enrollment and retention in clinical trials depends on many factors, including:

- the extent of the ongoing COVID-19 pandemic, see —“*The COVID-19 pandemic could adversely impact our business, including our preclinical studies, clinical trials and operations*”;
- the subject eligibility criteria defined in the protocol;
- the size of the subject population required for analysis of the trial's primary endpoints;
- the nature of the trial protocol, trial design, side effects or other results that may arise in development;
- the existing body of safety and efficacy data with respect to the product candidate;
- the proximity of subjects to clinical sites;
- our ability to recruit clinical trial investigators with the appropriate competencies, motivation and experience;
- clinicians' and subjects' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drug that may be approved for the indications we are investigating;
- competing clinical trials being conducted by other companies or institutions;
- our ability to obtain and maintain subject consents; and
- the risk that subjects enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of subjects available to us, because some people who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Furthermore, any negative results we may report in clinical trials of any product candidate may make it difficult or impossible to recruit and retain people in other clinical trials of that same product candidate. Delays or failures in planned subject enrollment or retention may result in increased costs or program delays, which could have a harmful effect on our ability to develop a product candidate or could render further development impossible.

Results of preclinical studies, clinical trials, or analyses may not be indicative of results that may be obtained in later trials or preclinical studies.

The results of preclinical studies, clinical trials, or analyses of the results from such trials may not be predictive of the results of later preclinical studies or clinical trials. Product candidates in later clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and prior clinical trials or having shown promising results based on analyses of data from earlier trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding earlier promising results. Our FX-322 Phase 2b results (FX-322-208), for example, showed no statistically significant difference at day 90 between those administered FX-322 versus those receiving placebo in the proportion of individuals that demonstrated an improvement in speech perception. In addition, conclusions based on promising data from analyses of clinical results, such as the prospective and *post hoc* analysis of data from our Phase 1/2 clinical trial of FX-322 for the treatment of SNHL (FX-322-201), may be shown to be incorrect in subsequent clinical trials that have pre-specified end points or may not be considered adequate by regulatory authorities. Further, we have in the past and may in the future abandon product candidates that we initially advanced for development based on positive preclinical results due to unfavorable results from additional preclinical studies. For example, we recently discontinued our FX-322 and FX-345 development programs after the results of the FX-322-208 clinical trial. Even if we complete later clinical trials as planned, we cannot be certain that their results will support the safety and efficacy requirements sufficient to obtain regulatory approval, and, as a result, our clinical development plans may be materially harmed.

Interim and preliminary “top-line” data from our clinical trials that we announce or publish from time to time may change as more subject data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, top-line or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line or preliminary data we previously published. As a result, top-line and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as subject enrollment continues and more subject data become available. Adverse differences between interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Any of our product candidates or component of a product candidate that we develop or the administration thereof, may cause serious adverse events or undesirable side effects, which may halt their clinical development, delay or prevent marketing approval, or, if approved, require them to be taken off the market, include safety warnings, or otherwise limit their sales.

Serious adverse events or undesirable side effects caused by our product candidates or component of a product candidate we develop could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Results of any clinical trial we conduct could reveal a high and unacceptable severity and prevalence of side effects.

If unacceptable side effects arise in the development of any product candidate, we, the FDA, or the IRBs or IECs at the institutions in which our studies are conducted, or the DSMB, if constituted for our clinical trials, could recommend a suspension or termination of our clinical trials, or the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of a product candidate for any or all targeted indications. In addition, drug-related side effects could affect subject recruitment or the ability of enrolled subjects to complete a trial or result in potential product liability claims. These side effects also may not be appropriately recognized or managed by the treating medical staff. We may have to train medical personnel regarding the proper administration protocol for our product candidates and to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in subject injury or death. Any of these occurrences may harm our business, financial condition, and prospects significantly.

Additionally, if an MS therapeutic or any other product candidates we develop receives marketing jurisdiction, and any such approval and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may suspend, withdraw, or limit approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require us to recall a product or we may decide to initiate a voluntary recall of a product;

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- regulatory authorities may require additional warnings on the label, such as a "black box" warning or contraindication;
- additional restrictions may be imposed on the marketing of the product or the manufacturing processes for the product or any component thereof;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a medication guide outlining the risks of such side effects for distributed subjects;
- we may be required to conduct post-market studies or agree to post marketing commitments;
- we could be sued and held liable for harm caused to subjects;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of a product candidate, if approved, and could significantly harm our business, results of operations, and prospects.

Disruptions at the FDA and other government agencies caused by funding shortages, changes in the federal administration or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs or the FDA experiences other delays, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of foreign and domestic manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays.

Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic or issue guidance materially affecting the conduct of clinical trials. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory

submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We may not be successful in our efforts to identify additional product candidates. Due to our limited resources and access to capital, we must prioritize development of certain product candidates, the choice of which may prove to be wrong and adversely affect our business.

Although we intend to explore additional product candidates based on our PCA approach, we may fail to identify viable new product candidates for clinical development for several reasons. If we fail to identify additional potential product candidates, our business could be materially harmed.

Research programs to develop additional product candidates based on our PCA approach require substantial technical, financial, and human resources whether or not they are ultimately successful. Our research programs may initially show promise in identifying potential indications or product candidates, yet fail to yield results for clinical development for several reasons, including:

- the research methodology used may not be successful in identifying potential indications or product candidates;

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- potential product candidates may, after further study, be shown to have harmful or unexpected adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources **narrower indication** than we possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify, and expand our product portfolio.

Because we have limited financial and human resources, we intend to initially focus on research programs and product candidates for a limited set of indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that could have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. For example, we may encounter delays in the process of selecting a product candidate for the treatment of MS and we may not achieve the timeline we currently anticipate for submitting an IND or comparable foreign equivalent. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

We have never obtained marketing approval for a product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any product candidate.

We have never obtained marketing approval for a product candidate. It is possible that the FDA may refuse to accept for substantive review any NDAs that we submit for our product candidates or may conclude after review of our data that our applications are insufficient to obtain marketing approval of our product candidates. We believe our approach of activating progenitor cells to treat conditions or diseases through cellular regeneration is novel and, as a result, the process for, and the outcome of, FDA approval is especially uncertain. If the FDA does not accept or approve our NDAs for our product candidates, it may require that we conduct additional clinical, preclinical, or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA that we submit may be delayed or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDAs.

Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing our product candidates, generating revenues, and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for our product candidates, which could significantly harm our business.

Even if we obtain FDA approval for a product candidate in the United States, we may never obtain approval for or commercialize the product candidate in any other jurisdiction, which would limit our ability to realize its full market potential.

In order to market any product in a particular jurisdiction, we or our collaborators must establish and comply with numerous and varying regulatory requirements regarding safety and efficacy on a country-by-country basis. Approval by the FDA in the United States does not ensure approval by comparable regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our or our collaborators' ability to obtain approval elsewhere. **seek**. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. **We may conduct one or more of our clinical trials with one or more trial sites that are located outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to conditions imposed by the FDA, and there can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and could delay or permanently halt our development of the applicable product candidates. Similarly, marketing approval by the FDA in the United States, if obtained, does not ensure**

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approval by regulatory authorities in other countries or jurisdictions. Approval processes vary among countries and can involve additional product candidate testing and validation and additional administrative review periods. Seeking foreign

Commercialization of any product candidates we may develop will also require obtaining manufacturing supply, capacity and expertise; building of a commercial organization; and significant marketing efforts. If we do not successfully commercialize any product candidates we may develop, we could experience a material harm to our business.

RNA editing is a novel technology that is not yet clinically validated for human therapeutic use. The approaches we take to discover and develop novel therapeutics are unproven and may never lead to marketable products.

We are focused on developing therapies based on RNA editing. Although there have been significant advances in the field of gene editing in recent years, RNA editing technologies are new and largely unproven. The technologies that we have developed have not yet been clinically tested, nor are we aware of any clinical trials for safety or efficacy having been completed by third parties using RNA editing or similar technologies. The scientific evidence to support the feasibility of developing product candidates based on these technologies is both preliminary and limited. Successful development of product candidates by us will require solving a number of issues, including optimizing the efficiency and specificity of such product candidates, and ensuring the therapeutic selectivity of such product candidates. There can be no assurance we will be successful in solving any or all of these issues.

We have concentrated our research efforts to date on preclinical work to bring therapeutics to the clinic for our initial indications, and our future success is highly dependent on the successful development of OPERA, our RNA editing platform, as well as cellular delivery methods and therapeutic applications of that technology. While some of the existing, non-RNA editing, gene editing technologies developed by third parties have progressed to clinical trials, they continue to suffer from various limitations, and such limitations may affect our future success. While a number of clinical trials for oligonucleotide products conducted by other companies have not been successful, some have received regulatory approval. The pharmacological properties ascribed to the product candidates we are testing or will test in the future may not be positively demonstrated in clinical trials in patients, and they may interact with human biological systems in unforeseen, ineffective or harmful ways. If our product candidates prove to be ineffective, unsafe or commercially unviable, our OPERA platform and our pipeline would have little, if any, value, which would substantially harm our business, financial condition, results of operations and prospects. We may decide to alter or abandon our initial programs as new data becomes available and we gain experience in developing base editing therapeutics. We cannot be sure that our technologies will yield satisfactory products that are safe and effective, scalable or profitable in our initial indications or any other indication we pursue.

Development activities in the field of RNA editing are currently subject to a number of risks related to the ownership and use of certain intellectual property rights that are subject to patent reexamination and inter partes proceedings in the United States and opposition proceedings in Europe. For additional information regarding the risks that may apply to our and our licensors' intellectual property rights, see "—Risks Related to Intellectual Property."

We are very early in our development efforts, and our preclinical studies and clinical trials may not be successful. If we are unable to commercialize our product candidates or experiences significant delays in doing so, our business will be materially harmed.

We are very early in our development of product candidates and have focused our efforts to date on platform development, discovery, research, and preclinical development. Currently, all of our programs are still in the research or preclinical stage of development. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development, marketing approval and eventual commercialization of our product candidates, which may never occur. We have not yet generated revenue from product sales or otherwise, and we may never be able to develop or commercialize a marketable product.

Commencing clinical trials in the United States is subject to acceptance by the FDA of an IND and finalizing the trial design based on discussions with the FDA and other regulatory authorities. In the event that the FDA requires us to complete additional preclinical studies or we are required to satisfy other FDA requests prior to commencing clinical trials, the start of our first clinical trials may be delayed or we may be unsuccessful obtaining clearance to proceed into clinical development. Even after we receive and incorporate guidance from these regulatory authorities, the FDA or other regulatory authorities could result in difficulties and increased costs for disagree that we have satisfied their requirements to commence any clinical trial or change their position on the acceptability of our trial designs or the clinical endpoints selected, which may require us and require to complete additional preclinical studies or clinical trials, delay the enrollment of our clinical trials, abandon our clinical development plans or meet stricter approval conditions than we currently expect. There are equivalent processes and risks applicable to CTAs in other countries, including countries in the European Union, or EU.

Commercialization of any product candidates we may develop will require preclinical and clinical development; regulatory and marketing approval in multiple jurisdictions, including by the FDA and the EMA; manufacturing supply, capacity and expertise; a commercial organization; and significant marketing efforts. The success of our product candidates will depend on many factors, including the following:

- timely and successful completion of preclinical studies, including toxicology studies, biodistribution studies and minimally efficacious dose studies in animals, where applicable;
- effective INDs or comparable foreign applications that allow commencement of our planned clinical trials or future clinical trials for any product candidates we may dev

- successful enrollment and completion of clinical trials, including under the FDA's current GCPs, current Good Laboratory Practices, or GLPs, and any additional regulatory requirements from foreign regulatory authorities;
- positive results from our future clinical trials that support a finding of safety and effectiveness and an acceptable risk-benefit profile in the intended populations;
- receipt of marketing approvals from applicable regulatory authorities;
- establishment of arrangements through our own facilities or with third-party manufacturers for clinical supply and, where applicable, commercial manufacturing capabilities;
- establishment, maintenance, defense and enforcement of patent, trademark, trade secret and other intellectual property protection or regulatory exclusivity for any product candidates we may develop;
- commercial launch of any product candidates we may develop, if approved, whether alone or in collaboration with others;
- acceptance of the benefits and use of the product candidates we may develop, including method of administration, if and when approved, by patients, the medical community and third-party payors;
- effective competition with other therapies;
- maintenance of a continued acceptable safety, tolerability and efficacy profile of any product candidates we may develop following approval; and
- establishment and maintenance of healthcare coverage and adequate reimbursement by payors.

If we do not succeed in one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize any product candidates we may develop, which **could** materially harm our business.

Any product candidates we develop may fail in preclinical or clinical development or be **costly delayed to a point where they do not become commercially viable.**

Before obtaining regulatory approval for the commercial distribution of any of our product candidates, we must conduct, at our own expense, extensive preclinical studies and **time-consuming**. **Regulatory requirements** clinical trials to demonstrate the safety and efficacy in humans of our product candidates. Preclinical and clinical testing are expensive, difficult to design and implement, can **vary widely from country** take many years to **country** complete, are uncertain as to outcome, and the historical failure rate for drugs in preclinical and clinical development is high. For example, we depend on the availability of non-human primates to conduct certain preclinical studies. Over the past several years there has been an increasing global shortage of non-human primates available for drug development that has matured into an acute global supply chain issue. The supply of these non-human primates is currently constrained due to factors such as their limited worldwide availability, domestic regulatory restrictions and trade relations. If we are unable to obtain access to a sufficient supply of these non-human primates in a timely manner or at all, our timelines and our ability to complete preclinical testing and submit IND or CTA applications may be adversely affected.

The development of one or more of our product candidates can fail at any stage of testing. We may experience numerous unforeseen events during, or as a result of, preclinical studies and clinical trials that could delay or prevent regulatory approval or our ability to commercialize our product candidates, including:

- our preclinical studies or clinical trials may produce negative or inconclusive results, including results that may not meet the **introduction** level of significance or clinical benefit required by the FDA or other regulators, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials, or we may abandon projects that we had expected to be promising;

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- delays in filing INDs or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators or institutional review boards, or IRBs order to commence a clinical trial at a prospective trial site, or their suspension or termination of a clinical trial once commenced;
- conditions imposed on us by the FDA or comparable foreign authorities regarding the scope or design of our **products** clinical trials;
- divergent views between FDA and other homologue regulatory authorities as to the objectives and/or design of the clinical trials required in **those countries**. **We do not have** support of marketing registration;
- problems in obtaining or maintaining IRB approval of trials;
- delays in enrolling patients or volunteers into clinical trials, and variability in the number and types of patients eligible for clinical trials;
- an inability to open study sites, or enroll, treat, and monitor patients due to local restrictions, including as a result of COVID-19 or any other pandemic or endemic or other events, such as the Russian invasion of Ukraine or Israeli-Hamas conflict;
- delays in developing and receiving regulatory approval for companion diagnostic tests, to the extent such tests are needed, to identify patients for our clinical trials;
- high drop-out rates for patients in clinical trials and substantial missing data;
- negative or inconclusive results from our clinical trials or the clinical trials of others for product candidates **approved** similar to ours;
- failure of future clinical trials to confirm positive results, if any, from earlier preclinical studies and clinical trials;

- inability to consistently manufacture, inadequate supply, or unacceptable quality of product candidate materials or other materials necessary for **sale** the conduct of our clinical trials;
- greater than anticipated clinical trial costs;
- serious and unexpected side effects that may or may not be related to the product candidate being tested that are experienced by participants in **any jurisdiction, including international markets**, our clinical trials or by individuals using drugs similar to our product candidates;
- poor or disappointing effectiveness of our product candidates during clinical trials;
- unfavorable outcome of FDA or other regulatory agency inspection and **we do not have experience in obtaining regulatory approval in international markets. If we fail to obtain regulatory approval of a manufacturing or clinical trial site or other records relating to the clinical investigation;**
- failure of our third-party contractors, investigators, or collaboration partners to comply with regulatory requirements or otherwise meet their contractual obligations in **international markets** a timely manner, or at all;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around manufacturing, preclinical, or clinical testing generally or with respect to **obtain** our product candidates class, in particular; or
- varying interpretations of data by the FDA and similar foreign regulatory agencies.

If we do not successfully conduct clinical development, we will not be able to market and sell products derived from our product candidates or generate product revenues. Even if we do successfully complete clinical trials, those results are not necessarily predictive of results of additional trials that may be needed before we can submit an application for regulatory approval to the FDA or foreign regulatory agencies. If the development of any of our product candidates fails or is delayed to a point where such product candidate is no longer commercially viable, our business may be materially harmed.

We may not be able to conduct clinical trials successfully due to various process-related factors that could negatively impact our business plans.

The successful initiation and completion of any of our clinical trials, within timeframes consistent with our business plans, is dependent on various factors, which include, but are not limited to, our ability to:

- retain and recruit employees, contractors or consultants with the required level of knowledge and experience;

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- retain and recruit, in a timely manner, a sufficient number of patients necessary to conduct a clinical trial, which is a function of many factors, including the impact of the COVID-19 endemic, the proximity of participants to clinical sites, the size of the relevant population, the eligibility criteria for the trial, possible adverse effects from treatments, the existence of competing clinical trials, the involvement of patient advocacy groups, the availability of new or alternative treatments, lack of efficacy, personnel issues and ease of participation in our clinical trials;
- manage the impact of the COVID-19 endemic or other global health pandemics or endemics on our early-stage discovery efforts and clinical trials; open study sites, a enroll, treat, and monitor patients due to local restrictions implemented in response to remaining COVID-19 effects or other global health pandemics or endemics;
- develop companion diagnostic tests for use with certain of our product candidates or identify partners with such expertise;
- manufacture and maintain a sufficient amount of clinical material, internally or through third parties;
- ensure adherence to trial designs and protocols agreed upon and approved by regulatory authorities and applicable regulatory and legal guidelines;
- apply the appropriate pharmacovigilance measures in case of adverse effects emerging during a clinical trial;
- execute clinical trial designs and protocols approved by regulatory authorities without deficiencies;
- timely and effectively contract with (under reasonable terms), manage and work with investigators, institutions, hospitals and the CROs involved in the clinical trial;
- negotiate contracts and other related documents with clinical trial parties and IRBs, CRO agreements and site agreements, which can be subject to extensive negotiation that could cause significant delays in the clinical trial process, with terms possibly varying significantly among different trial sites and CROs and possibly subjecting us to various risks; and
- conduct clinical trials in a cost-effective manner, including management of foreign currency risk in clinical trials conducted in foreign jurisdictions and cost increases due to unforeseen or unexpected complications such as enrollment delays, or needing to outsource certain functions during the clinical trial.

If we are not able to manage the clinical trial process successfully, our business plans could be delayed or be rendered unfeasible for us to execute within our planned or required **approvals, time frames, or if at all.**

If we cannot successfully manufacture our product candidates for our research and development and preclinical activities, or manufacture sufficient amounts of our product candidates to meet our clinical requirements and timelines, our business may be materially harmed.

In order to develop our product candidates, apply for regulatory approvals in international markets are delayed, and commercialize our target market will be reduced and product candidates, we will need to develop, contract for, or otherwise arrange for the necessary manufacturing and supply capabilities. In addition to the oligonucleotides that we manufacture internally, we may utilize CMOs to manufacture the oligonucleotides required for our preclinical studies and clinical trials. There are a limited number of manufacturers that supply oligonucleotides. There are risks inherent in pharmaceutical manufacturing that could affect our ability or the ability of our CMOs to meet delivery time requirements or provide adequate amounts of material to meet our clinical trial demands on our projected timelines. Included in these risks are potential synthesis and purification failures and/or contamination during the manufacturing process, as well as other issues with our facility or the CMOs' facilities and ability to comply with the applicable manufacturing requirements and quality standards, which could result in unusable product and cause delays in our manufacturing timelines and ultimately delay our clinical trials, as well as result in additional expense. To manufacture our oligonucleotides, we rely on third parties to supply the required raw materials. We will likely need to secure alternative suppliers for these raw materials, and such alternative suppliers are limited and may not be readily available, or we may be unable to enter into agreements with them on reasonable terms and in a timely manner. For example, we source certain materials used in the manufacture of our products from China and other countries outside of the United States; the coronavirus outbreak or other similar global disruptions has made access to our existing supply chain difficult and further supply chain disruptions could impact our business. Additionally, our cost of goods development is at an early stage. The actual cost to manufacture and process our product candidates could be greater than expected and could materially and adversely affect the commercial viability of our product candidates.

Moreover, we license the LNP technology used to deliver KRRO-110 from a third party. Although our current partner, Genevant Sciences GmbH, or Genevant, is a well established leader in the LNP space, and our preclinical studies of this LNP delivery technology have shown improved dose-dependent efficacy with reduced clinical chemistry and adverse events, there is

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no guarantee that this will be replicated in clinical trials. There is also no guarantee that we will continue to source the LNP delivery system for KRRO-110 from Genevant. The process of establishing and maintaining collaborative relationships and identifying and securing access to optimized delivery systems that are fit-for-purpose is difficult, time-consuming, and involves significant uncertainty. If the current arrangement with Genevant is terminated, our clinical development, manufacturing, or commercialization efforts for KRRO-110 could be delayed or terminated, while we secure an alternative delivery system, which could have a material adverse impact on our clinical development plans and business.

The process of manufacturing oligonucleotides is complex and we may encounter difficulties in production, particularly with respect to process development or scaling-up of our manufacturing capabilities.

The process of manufacturing oligonucleotides is complex, highly-regulated and subject to multiple risks. The complex processes associated with the manufacture of our product candidates expose us to various manufacturing challenges and risks, which may include delays in manufacturing adequate supply of our product candidates, limits on our ability to increase manufacturing capacity, and the potential for product failure and product variation in quality that may interfere with preclinical studies and clinical trials, along with additional costs. We may also make changes to our manufacturing process or the delivery system we use at various points during development, and even after commercialization, for various reasons, such as optimizing costs, achieving scale, decreasing processing time, increasing manufacturing success rate, or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of current or future clinical trials, or the performance of the product, once commercialized. In some circumstances, changes in the manufacturing or delivery system may require us to perform ex vivo comparability studies, and/or conduct animal studies, and to collect additional data from patients prior to undertaking more advanced clinical trials. For instance, changes in our manufacturing process during the course of clinical development may require us to show the comparability of the product used in earlier clinical trials or at earlier portions of a trial to the product used in later clinical trials or later portions of the trial. We may also make further changes to our manufacturing or delivery system before or after commercialization, and such changes may require us to show the comparability of the resulting product to the product produced via earlier manufacturing processes and supplied or delivery system used in clinical studies. We may be required to collect additional preclinical and/or clinical data from any modified process prior to obtaining marketing approval for the product candidate produced with such modified process. If preclinical and/or clinical data are not ultimately comparable to those seen in the earlier trials, we may be required to make further changes to our process and/or undertake additional clinical testing, either of which could significantly delay the clinical development or commercialization of the associated product candidate.

Although we continue to build on our experience in manufacturing oligonucleotides, we have limited experience as a company manufacturing product candidates for commercial supply. We may never be successful in manufacturing product candidates in sufficient quantities or with sufficient quality for commercial use. Our manufacturing capabilities could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, operator error, natural disasters, unavailability of qualified personnel, difficulties with logistics and shipping, problems regarding yields or stability of product, contamination or other quality control issues, power failures, and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business.

Furthermore, compliance with cGMP requirements and other quality issues may arise during any internal efforts to scale-up manufacturing, and with our current or any future CMOs. If contaminants are discovered in our supply of our product candidates or in the manufacturing facilities of our CMOs, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our product candidates will not occur in the future. Additionally, our CMOs may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or

unstable political environments. If our CMOs were to encounter any of these difficulties, our ability to provide our product candidate to patients in clinical trials, or to provide product for treatment of patients once approved, would be jeopardized.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial resources, we intend to focus on developing product candidates for specific indications that we identify as most likely to succeed, in terms of both regulatory approval and commercialization. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that may prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through

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collaboration, licensing or other royalty arrangements in cases in which we would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We have not tested any of our proposed delivery methods or gene editing approaches in clinical trials and any favorable results we may have may not be predictive of results that may be observed in later preclinical studies or clinical trials.

The scientific evidence to support the feasibility of developing product candidates using our RNA editing technology is both preliminary and limited. We have not tested any of our potential delivery modalities or gene editing approaches in clinical trials and any favorable results we may have may not be predictive of results that may be observed in later preclinical studies or clinical trials. For example, we may use LNPs or other delivery modalities to deliver our product candidates. While LNPs have been validated clinically to deliver oligonucleotides, such as siRNA, they have not been clinically proven to deliver oligonucleotides for RNA editing, such as our product candidates.

In addition, our RNA editing technology itself may lead to other issues, such as inability to deliver the desired efficacy or safety-related consequences as it is tested in clinical trials. We have not generated any clinical trial results to date. The design of a clinical trial can determine whether its results will support approval of a product candidate and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. Furthermore, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. Many product candidates that initially showed promise in early stage testing for treating a variety of diseases have later been found to lack efficacy or to cause side effects that prevented further clinical development of the product candidates.

Our future product candidates may cause undesirable and unforeseen side effects or be perceived by the public as unsafe, which could delay or prevent their advancement into clinical trials or regulatory approval, limit the commercial potential or result in significant negative consequences.

We have not evaluated any product candidates in human clinical trials. Moreover, there have been only a limited number of clinical trials involving the use of gene editing technologies and none involving RNA editing technology similar to our technology. It is impossible to predict when, or if, any product candidates we may develop will prove safe in humans. In the genetic medicine field, there have been several significant adverse events from gene therapy treatments in the past, including reported cases of leukemia and death. There can be no assurance that RNA editing technologies will not cause undesirable side effects, such as lymphoma, leukemia, or other cancers, or other aberrantly functioning cells.

If any such adverse events occur, our future clinical trials could be suspended or terminated. If we are unable to demonstrate that any adverse events were caused by the administration process or related procedures, the FDA, the European Commission, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, any future product candidates for any or all targeted indications. Even if we can demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete any future trial. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may adversely affect our business, financial condition, results of operations and prospects significantly.

Additionally, if any of our future product candidates receives marketing approval, the FDA could require us to adopt a REMS to ensure that the benefits of the product outweigh its risks, which may include, for example, a Medication Guide outlining the risks of the product for distribution to patients and a communication plan to health care practitioners, or other elements to assure safe use of the product. Furthermore, if we or others later identify undesirable side effects caused by any of our future product candidates, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such product candidate;
- we may be required to change the way a product candidate is administered or conduct additional clinical trials;

- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly.

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If we are unable to successfully identify patients who are likely to benefit from therapy with any product candidates we develop, or experience significant delays in doing so, we may not realize the full market commercial potential of any medicines we may develop.

Our success may depend, in part, on our ability to identify patients who are likely to benefit from therapy with any medicines we may develop, which may require those potential patients to have their DNA analyzed for the presence or absence of a particular sequence. If we, or any third parties that we engage to assist us, are unable to successfully identify such patients, or experience delays in doing so, then:

- our ability to develop any product candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our clinical trials; and
- we may not realize the full commercial potential of any product candidates we develop, develop that receive marketing approval if, among other reasons, we are unable to appropriately select patients who are likely to benefit from therapy with our medicines.

As a result of these factors, we may be unable to successfully develop and realize the commercial potential of any product candidates we may identify and develop, and our business, financial condition, results of operations, and prospects would be materially adversely affected.

If we are unable to successfully develop or obtain regulatory approval for companion diagnostic tests for our product candidates, or experience significant delays in doing so, our clinical trials may be delayed and our business could be materially harmed.

The development programs for some of our product candidates contemplate the development of companion diagnostic tests, which are assays or tests to identify an appropriate patient population. If safe and effective use of any of our product candidates we may develop depends on a companion diagnostic, we may not receive marketing approval, or marketing approval may be delayed, if we are unable to or are delayed in developing, identifying, or obtaining regulatory approval or clearance for the companion diagnostic product for use with our product candidate. Identifying a manufacturer of the companion diagnostic and entering into an agreement with the manufacturer could also delay the development of our product candidates.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell any future product candidates, we may be unable to generate any revenues.

We currently do not have an organization for the sales, marketing and distribution of any future product candidates and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. To market any products that may be approved, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. With respect to certain of our current programs as well as future programs, we may rely completely on an alliance partner for sales and marketing. In addition, although we intend to establish a sales organization if we are able to obtain approval to market any product candidates, we may enter into strategic alliances with third parties to develop and commercialize any future product candidates, including in markets outside of the United States or for other large markets that are beyond our resources. This will reduce the revenue generated from the sales of these products.

Any future strategic alliance partners may not dedicate sufficient resources to the commercialization of our product candidates or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective alliances to enable the sale of our product candidates to healthcare professionals and in geographical regions, including the United States, that will not be covered by our own marketing and sales force, or if our potential future strategic alliance partners do not successfully commercialize the product candidates, our ability to generate revenues from product sales will be adversely affected.

If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

Even if we receive regulatory approval to market our product candidates, the market may not be receptive to our product candidates upon their commercial introduction, which will prevent us from becoming profitable.

Our product candidates are based upon new discoveries, technologies and therapeutic approaches. Key participants in pharmaceutical marketplaces, such as physicians, third-party payors and consumers, may not adopt a product intended to improve

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therapeutic results that is based on the technology employed by oligonucleotides. As a result, it may be more difficult for us to convince the medical community and third-party payors to accept and use our product, or to provide favorable reimbursement.

35 Other factors that we believe will materially affect market acceptance of our product candidates include:

- the timing of our receipt of any regulatory approvals, the terms of any approvals and the countries in which approvals are obtained;
- the ability to consistently manufacture our products within acceptable quality standards;
- the safety and efficacy of our product candidates, as demonstrated in clinical trials and as compared with alternative treatments, if any;
- the incidence, seriousness and severity of any side effects;
- the relative convenience and ease of administration of our product candidates;
- the willingness of patients to accept potentially new routes of administration and their risk tolerance as it relates to potentially serious side effects;
- the success of our physician education programs;
- the availability of government and third-party payor coverage and adequate reimbursement;
- the pricing of our products, particularly as compared to alternative treatments; and
- the availability of alternative effective treatments for the diseases that product candidates we develop are intended to treat and the relative risks, benefits and costs of treatments.

In addition, our estimates regarding the potential market size may be materially different from what we currently expect by the time we commence commercialization, which could result in significant changes in our business plan and may significantly harm our results of operations and financial condition.

The pharmaceutical industry is intensely competitive. If we are unable to compete effectively with existing drugs, new treatment methods and new technologies, we may be unable to commercialize successfully any drugs that we develop.

The pharmaceutical industry is intensely competitive and rapidly changing. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are pursuing the development of novel drugs for the same diseases that we are targeting or expect to target. Many of our competitors have:

- much greater financial, technical and human resources than we have at every stage of the discovery, development, manufacture and commercialization of products;
- more extensive experience in designing and conducting preclinical studies and clinical trials, obtaining regulatory approvals, and manufacturing, marketing and selling pharmaceutical products;
- product candidates that are based on previously tested or accepted technologies;
- products that have been approved or are in late stages of development; and
- collaborative arrangements in our target markets with leading companies and research institutions.

We will face intense competition from drugs that have already been approved and accepted by the medical community for the treatment of the conditions for which we may develop therapies. We also expect to face competition from new drugs that enter the market. We believe a significant number of drugs are currently under development, and may become commercially available in the future, for the treatment of conditions that our current or future product candidates are or may be designed to treat. These drugs may be more effective, safer, less expensive, or marketed and sold more effectively, than any products we develop.

Our competitors may develop or commercialize products with significant advantages over any products we are able to develop and commercialize based on many different factors, including:

- the safety and effectiveness of our products relative to alternative therapies, if any;
- the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration;

- the timing and scope of regulatory approvals for these products;

- the availability and cost of manufacturing, marketing and sales capabilities;
- price;
- more extensive coverage and higher levels of reimbursement; and
- patent position.

Our competitors may therefore be more successful in commercializing their products than we are, which could adversely affect our competitive position and business. Competitive products may make any products we develop obsolete or noncompetitive before we can recover the expenses of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute on our business plan.

The pricing, insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate product revenue.

We expect that coverage and reimbursement by third-party payors will be essential for most patients to be able to afford any gene therapies for which we are able to successfully complete clinical development. Accordingly, sales of any future products will depend substantially, both domestically and internationally, on the extent to which the costs of any such products will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or will be reimbursed by government authorities, private health coverage insurers and other third-party payors. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on its investment. If we are unable to establish or sustain coverage and adequate reimbursement for any future product candidates from third-party payors, the adoption of those product candidates and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products in both the United States and globally. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in the United States, the EU, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as its product candidates. Moreover, increasing efforts by governmental and third-party payors, in the United States and internationally, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of certain third-party payors, such as health maintenance organizations, and additional legislative changes. For an overview and discussion of the regulatory framework for pricing and reimbursement, see Item 1 “Business—Government Regulation—Patients Rely on Insurance Coverage by Third-Party Payors (third-party payors include Medicare and Medicaid (government payors) and commercial insurance companies such as Blue Cross Blue Shield, Humana, Cigna, etc.) to Pay for Products.”

If the market opportunities for any product candidates we may develop are smaller than we believe they are, our potential revenues may be adversely affected, and our business may suffer.

Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with product candidates we may develop, are based on estimates. These estimates may prove to be incorrect and new studies may change the estimated incidence or prevalence of these diseases. Additionally, our estimates regarding the potential market size may be materially different from what we currently expect by the time we commence commercialization. The number of patients in the United States, Europe, and elsewhere may turn out to be lower than expected, and patients may not be amenable to treatment with our product candidates, or may become increasingly difficult to identify or gain access to, all of which would adversely affect our business, financial condition, results of operations, and prospects.

While we intend to seek designations for our product candidates with the FDA and comparable foreign regulatory authorities that are intended to confer benefits such as a faster development process or an accelerated regulatory pathway, there can be no assurance that we will successfully obtain such designations. In addition, even if one or more of our product candidates are granted such designations, we may not be able to realize the intended benefits of such designations.

The FDA and comparable foreign regulatory authorities offer certain designations for product candidates that are designed to encourage the research and development of product candidates that are intended to address conditions with significant unmet medical need. These designations include fast track, or breakthrough therapy, among others, and may confer benefits such as additional interaction with regulatory authorities, a potentially accelerated regulatory pathway and priority review. However, there can be no assurance that we will successfully obtain such designations for any product candidates. See Item 1 “Business—Government Regulation—Expedited Development and Review Programs for Drugs” for more information regarding these designations. While such designations could expedite the development or approval process, they generally do not change the standards for approval. Even if we obtain such designations for one or more of our product candidates, there can be no assurance that we will realize their intended benefits.

In the future, we may also seek approval of product candidates under the FDA’s accelerated approval pathway or request priority review. There can be no assurance that FDA would allow any of the product candidates we may develop to proceed on an accelerated approval pathway or grant priority review, and even if FDA did allow such pathway,

there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. Moreover, even if we received accelerated approval, any post-approval studies required to confirm and verify clinical benefit may not show such benefit, which could lead to withdrawal of any approvals we have obtained. Receiving accelerated approval does not assure that the product's accelerated approval will eventually be converted to a traditional approval.

In addition, in the EU, we may seek to participate in The PRiority Medicines, or PRIME scheme for our product candidates. The PRIME scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation, where the marketing authorization application will be made through the centralized procedure in the EU. There is no guarantee, however, that our product candidates would be deemed eligible for the PRIME scheme and even if we do participate in the PRIME scheme, where during the course of development a medicine no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn. PRIME eligibility does not change the standards for product approval, and there is no assurance that any such designation or eligibility will result in expedited review or approval. For more information regarding PRIME and the EU regulatory framework, see Item 1 "Business—Government Regulation—Regulation Outside of the United States."

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn, or additional global financial crises, could result in a variety of risks to our business, including weakened demand for any future product candidates, if approved, or our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in clinical or commercial supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our business may be impacted by macroeconomic conditions, including fears concerning the financial services industry, inflation, rising interest rates and volatile market conditions, and other uncertainties beyond our control.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, in March 2023, Silicon Valley Bank Signature Bank and Silvergate Capital Corp. were each swept into receivership by the Federal Deposit Insurance Corporation and then a syndicate of U.S. banks infused \$30 billion in First Republic Bank; and later that same week, the Swiss Central Bank provided \$54 billion in covered loan and short-term liquidity facilities to Credit Suisse Group AG, all in an attempt to reassure depositors and calm fears of a banking contagion.

Our ability to effectively run our business could be adversely affected by general conditions in the global economy and in the financial services industry. Various macroeconomic factors could adversely affect our business, including fears concerning the banking sector, changes in inflation, interest rates and overall economic conditions and uncertainties. A severe or prolonged economic downturn could result in a variety of risks, including our ability to raise additional funding on a timely basis or on acceptable terms. A weak or declining economy could also impact third parties upon whom we depend to run our business. Increasing concerns over bank failures and bailouts and their potential broader effects and potential systemic risk on the banking sector generally and on the biotechnology industry and its participants may adversely affect our access to capital and our business and operations more generally. Although we assess our banking relationships as we believe necessary or appropriate, our access

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to funding sources in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general.

Risks Related to Regulatory, Legal, and Clinical Trials

Because we are developing oligonucleotides, which are considered a relatively new class of drugs, there is increased risk that the outcome of our clinical trials will not be sufficient to obtain regulatory approval.

The FDA and comparable ex-U.S. regulatory agencies have relatively limited experience with oligonucleotides, which may increase the complexity, uncertainty and length of the regulatory review process for any future product candidates. Even though the FDA issued two draft guidance documents in December 2021 relating to IND submissions for individualized antisense oligonucleotide drugs for severely debilitating or life-threatening genetic diseases, one with clinical focus, the other with chemistry manufacturing and controls focus, and in June 2022 a draft guidance on clinical pharmacology considerations for the development of oligonucleotide therapeutics, the FDA and its foreign counterparts have not yet established any definitive policies, practices or guidelines in relation to overall development considerations for RNA editing oligonucleotide therapies. The general lack of policies, practices or guidelines specific to oligonucleotides may hinder or slow review by the FDA or other foreign homologues of any regulatory filings that we may submit. Moreover, the FDA or other foreign homologues may respond to these submissions by defining requirements we may not have anticipated. Addressing such requirements could lead to significant delays in the development of our product candidates. In addition, because there may be approved treatments for some of the diseases for which we may seek

approval, in order to receive regulatory approval, we may need to demonstrate through clinical trials that the product candidates we develop to treat these diseases, if any, are not only safe and effective, but safer or more effective than existing products. Furthermore, in recent years, there has been increased public and political pressure on the FDA with respect to the approval process for new drugs. As a result of the foregoing factors, we may never receive regulatory approval to market and commercialize any product candidate. Even if we obtain regulatory approval, for any product candidate, we will still face extensive and ongoing regulatory requirements and obligations, which may result in significant additional expense, and any product candidates, if approved, may face future development and regulatory difficulties.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, and advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with current Good Manufacturing Practice, or cGMP, requirements relating to manufacturing, quality control, quality assurance, and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and Good Clinical Practice, or GCP, and requirements for any clinical trials that we conduct post-approval.

Even if marketing approval of a product candidate is granted, the approval may be for disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We may be required to perform additional or unanticipated clinical trials to obtain regulatory approval or be subject to limitations on the indicated uses for which the product candidate may be marketed or to the conditions of approval, including a requirement to implement a REMS. If a product candidate receives marketing approval, the accompanying label may limit the approved indicated use of the product, which could limit sales of the product. The FDA may also require costly additional post-marketing studies or clinical trials and surveillance other requirements to monitor the safety or efficacy of maintain such approval. As a product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use, and if we market our products for uses beyond their approved indications, result, we may be subject to enforcement action for off-label marketing. Violations never succeed in developing a marketable product, we may not become profitable and the value of the Federal Food, Drug, and Cosmetic Act, or FDCA, relating to the promotion of prescription drugs, may lead to FDA enforcement actions and investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.our common stock could decline.

In addition, later discovery Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of previously unknown adverse events or other problems with and commercialize our products, manufacturers, or manufacturing processes or failure to comply with product candidates and may affect the prices we may set.

Existing regulatory requirements, may yield various results, including:

- restrictions on manufacturing such products;
- restrictions on the labeling or marketing of products;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recalls or market withdrawals of products;
- fines, restitution, or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions, consent decrees, or the imposition of civil or criminal penalties.

Further, the FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of a our product candidate. candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained which would adversely affect our business, prospects, and ability to achieve or sustain profitability.

We also cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. The policies of the FDA and of other comparable regulatory authorities may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of a product candidate. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action, and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition, and results of operations. Furthermore, noncompliance by us or any collaborator with regulatory profitability. For more information, see Item 1 "Business—Governmental Regulation."

36 We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us. In addition, other legislative changes have been proposed and adopted since the Patient Protection and Affordable Care Act, or the ACA was enacted. We may choose to seek an expanded access program for our product candidates, or to utilize comparable rules in other countries that allow the use of a drug, on a named patient basis or under a compassionate use program.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Payors, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs and those methods are not always specifically adapted for new technologies such as gene therapy and therapies addressing rare diseases such as those we are developing. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval

requirements, including safety monitoring or pharmacovigilance, may also result in significant financial penalties, which would adversely affect our business.⁶¹

We process may seek Fast Track designation by significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Because we are developing product candidates in the field of genetic medicines in which there is little clinical experience, there is increased risk that the FDA, for the EMA or other regulatory authorities may not consider the endpoints of our clinical trials to provide clinically meaningful results and that these results may be difficult to analyze.

In order to proceed into clinical development of any future product candidates but we might not receive such a designation. However, such designation may not lead identify, we will need to a faster development submit INDs or comparable foreign applications to regulatory review or approval process.

If a drug is intended for the treatment of a serious condition authorities and nonclinical or obtain regulatory clearance to commence clinical data demonstrate the potential to address an unmet medical need for this condition, a drug sponsor may qualify for FDA Fast Track designation. Fast Track designation provides increased opportunities for sponsor meetings with the FDA during preclinical and clinical development, in addition to the potential for rolling review and priority review once a marketing application is filed. The FDA has broad discretion whether to grant Fast Track designation, and we may not receive such a designation for all of development. Because the product candidates for which we identify are based on novel gene-editing technology, we may request it. Moreover, even if we receive Fast Track designation, Fast Track designation does not ensure that be unsuccessful in obtaining clearance from regulatory authorities to proceed into clinical development. In order to commence clinical development, we will receive marketing approval need to identify success criteria and endpoints such that the FDA, the EMA or that approval other regulatory authorities will be granted within able to determine the clinical efficacy and safety profile of any particular time frame. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

We may seek a Breakthrough Therapy designation for an MS therapeutic or other product candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process.

We may seek a Breakthrough Therapy designation for an MS therapeutic if results from future clinical trials support such designation and we may seek a Breakthrough Therapy designation for other product candidates we may develop. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, As we are initially seeking to identify and develop product candidates to treat a serious condition, diseases in which there is little clinical experience using new technologies, and preliminary while we may have opportunities to discuss our clinical evidence indicates development plans with regulatory authorities prior to commencing clinical development, there is heightened risk that the drug FDA, the EMA or other regulatory authorities may demonstrate substantial improvement over existing therapies on one or more not consider the clinical trial endpoints that we propose to provide clinically significant endpoints, such as substantial treatment effects observed early in meaningful results (reflecting a tangible benefit to patients). In addition, the resulting clinical development. For drugs that have been designated as breakthrough therapies, interaction data and communication between results may be difficult to analyze.

Even if the FDA does find our success criteria to be sufficiently validated and clinically meaningful, we may not achieve the sponsor pre-specified endpoints to a degree of statistical significance. Furthermore, even if we do achieve the pre-specified criteria, we may produce results that are unpredictable or inconsistent with the results of the trial can help to identify non-primary endpoints or other relevant data. The FDA also weighs the most efficient path for clinical development while minimizing the number benefits of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by a product against its risks, and the FDA may also be eligible for priority review if supported by clinical data at view the time efficacy results in the NDA is submitted context of safety as not being supportive of regulatory approval. Other regulatory authorities in the EU and other countries may make similar comments with respect to the FDA.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe that a these endpoints and data. Any product candidate meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such a designation. Even if we receive Breakthrough Therapy

designation, the receipt of such designation may not result in a faster development or regulatory review or approval process compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if a product candidate qualifies as a Breakthrough Therapy, the FDA may later decide that it no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

The use of any product candidate candidates we may develop will be based on a novel technology that makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval. No gene editing therapeutic product has been approved in the United States or in Europe. Within the broader genome product field, only a limited number of gene therapy products, such as uniQure N.V.'s Glybera and Abecma from Bristol Myers Squibb and bluebird bio, have received marketing authorization or marketing approval from the European Commission or the FDA. Some of these products have taken years to register and have had to deal with significant issues in their post-marketing experience.

If preclinical studies or clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by patients, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- significant costs to defend the litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize a product candidate;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;

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- decreased market demand for any product; and
- loss of revenue.

The product liability insurance we currently carry, and any additional product liability insurance coverage we acquire in the future, may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for any product candidate, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim, or series of claims, brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operation and business, including preventing or limiting the commercialization of any product candidates we develop. may identify and develop fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidates.

Before obtaining marketing approval from regulatory authorities for the sale of any product candidates we may identify and develop, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The COVID-19 pandemic has caused outcome of preclinical testing and could continue to cause disruptions to our business, including our preclinical studies, early clinical trials may not be predictive of the success of later clinical trials, and operations and could adversely impact our financial condition and interim results of operations. a clinical trial do not necessarily predict final results.

The COVID-19 pandemic, Moreover, preclinical and government measures taken clinical data are often susceptible to varying interpretations and analyses. Many companies that have believed their product candidates performed satisfactorily in response, have had a significant impact, both direct and indirect, on business and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen.

Since March 2020, the majority of our employees have continued to work from home two to three days per week, while our laboratory employees have largely resumed a full in-person schedule in our Lexington, MA facility. We have also taken steps consistent with the FDA's updated industry guidance for conducting clinical trials.

If COVID-19 or its variants again spread in the United States and worldwide, and measures to mitigate the ongoing effects of the pandemic, such as stay home orders and/or advisories persist or are reintroduced, we may continue to experience disruptions and other effects on our business that could severely impact our business, operations, preclinical studies and clinical trials including have nonetheless failed to obtain marketing approval of their product candidates.

We and our collaborators, if any, may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize any product candidates we may identify and develop, including:

- delays **difficulties** in reaching a consensus with regulators on trial design;
- regulators, IRBs, or postponement in enrolling and retaining subjects in independent ethics committees may not authorize us or our **planned** investigators to commence clinical **trials**; trial or conduct a clinical trial at a prospective trial site;
- delays **difficulties** in reaching or **postponement** in failing to reach agreement on acceptable clinical **site** initiation, including **difficulties** in recruiting trial contracts or clinical **investigators** trial protocols with prospective CROs and clinical **site staff**; trial sites;

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- clinical trials of any product candidates we may develop may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development or research programs;
- **diversion of healthcare resources away from the** difficulty in designing well-controlled clinical trials due to ethical considerations that may render it inappropriate to conduct clinical trials; a trial with a control arm that can be effectively compared to a treatment arm;
- **interruption** difficulty in designing clinical trials and selecting endpoints for diseases that have not been well-studied and for which the natural history and course of **key** clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others; interruption of clinical trial subject visits and study procedures, which may impact the **integrity** of subject data and clinical study endpoints; disease is poorly understood
- **interruption** the number of patients required for clinical trials of any product candidates we may develop may be larger than we anticipate; enrollment of suitable participants in these clinical trials, which may be particularly challenging for some of the rare genetically defined diseases we are targeting in our most advanced programs, may be delayed or slower than we anticipate; or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators, IRBs, or independent ethics committees may require that we or our investigators suspend or terminate clinical research or clinical trials of any product candidate we may develop for various reasons, including noncompliance with regulatory requirements, a finding of undesirable side effects or other unexpected characteristics, or the participants are being exposed to unacceptable health risks or after an inspection of our clinical trial operations or trial sites;
- the cost of clinical trials of any product candidates we may develop may be greater than we anticipate;
- the supply or quality of any product candidates we may develop or other materials necessary to conduct clinical trials of any product candidates we may develop may be insufficient or inadequate, including as a result of delays in the **operations** testing, validation, manufacturing, and delivery of the **FDA** or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our **any** product candidates from our contract manufacturing organizations due to **we may develop** to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- interruptions in planned trials due to restricted or limited operations at our laboratory facility;
- continual changes to operating requirements and related expenses, limitations in employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people and resulting losses of productivity and employee work culture;
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- refusal of the FDA, or other government agencies, to accept data from clinical trials in these affected geographies;
- interruption or delayed to our sourced discovery and clinical activities, and;
- inability to obtain additional financing or access the financial markets.

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The global outbreak of COVID-19 continues to rapidly evolve and continues to have indeterminable adverse effects on general commercial activity and the world economy. Due to the uncertain nature of the effects of the outbreak, particularly in the United States, enrollment, participation and retention in our planned trials may be reduced, and for a number of the clinical sites halted for an unknown period of time. Any reduction in enrollment, participation and retention and any halts may delay our planned clinical trials and our development plans for an MS therapeutic and any other product candidates, which could have an adverse impact on our business and results of operations.

The extent to which COVID-19 may continue to impact our business, preclinical studies, planned clinical trials and operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ongoing and ultimate geographic spread of the disease, duration of the outbreak, including future waves of infection, new variant strains of the underlying virus, travel restrictions and social distancing in the United States and other countries, business closures by us or business disruptions, adoption and effectiveness of vaccines and other actions taken in the United States and other countries to contain, treat and mitigate the spread of COVID-19. In addition, if we or any of the by third parties with whom we engage were have contracted to experience shutdowns perform certain of those functions;

- delays in having patients complete participation in a trial or additional business disruptions; return for post-treatment follow-up;
- clinical trial sites dropping out of a trial;

- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- occurrence of serious adverse events associated with any product candidates we may develop that are viewed to outweigh their potential benefits;
- occurrence of serious adverse events in trials of the same class of agents conducted by other sponsors; and
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

If we or our ability collaborators are required to conduct additional clinical trials or other testing of any product candidates we may develop beyond those that we currently contemplate, if we or our business in collaborators are unable to successfully complete clinical trials or other testing of any product candidates we may develop, or if the manner and on the timelines presently planned could be materially and negatively impacted, which could have a material adverse effect on our business and our financial results. The COVID-19 pandemic has resulted in a widespread health crisis that has adversely affected the economies and financial markets worldwide, resulting in an economic downturn that could continue to significantly impact our business, financial condition and results of operations. To the extent the COVID-19 pandemic adversely affects these trials or tests are not positive or are only modestly positive or if there are safety concerns, we or our business, financial condition and results of operations, it collaborators may:

- be delayed in obtaining marketing approval for any such product candidates we may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

Risks related to commercialization

We face significant competition from biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to acquire, develop and or not obtain marketing approval for new products on a cost-effective basis and to market them successfully. If a product candidate develop is approved, we will face intense competition from a variety of businesses, including large, fully integrated pharmaceutical companies, specialty pharmaceutical companies, and early-stage companies, particularly if the early-stage company has a collaborative arrangement with a large and established company. We are aware several companies developing programs with research and development efforts to treat MS through the regeneration of myelin. If we successfully develop and, if approved, commercialize an MS therapeutic, it may compete, or potentially be used in conjunction with, currently marketed therapeutics and any new therapeutics that may become available in the future.

Competition could render any product candidate we develop obsolete, less competitive, or uneconomical. Our competitors may, among other things:

- have significantly greater name recognition and financial, manufacturing, marketing, product development, technical, and human resources than we do;
- more effectively recruit and retain qualified scientific and management personnel;
- more effectively establish clinical trial sites and subject registration;
- develop and commercialize products that are safer, more effective, less expensive, more convenient, or easier to administer, or have fewer or less severe effects; at all;
- obtain quicker regulatory approval; approval for indications or patient populations that are not as broad as intended or desired;
- better protect their patents and intellectual property; obtain approval with labeling that includes significant use or acquire technologies that are complementary, distribution restrictions or necessary for, our programs; safety warnings, including boxed warnings;
- implement more effective approaches; be subject to sales, marketing, pricing, coverage, and reimbursement; changes in the way the product is administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the product or impose restrictions on our distribution in the form of a REMS or through modification to an existing REMS;

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- be sued; or
- form more advantageous strategic alliances or collaborations, experience damage to our reputation.

If Product development costs will also increase if we are or our collaborators experience delays in clinical trials or other testing or in obtaining marketing approval. We do not know whether any clinical trials will begin as planned, will need to effectively compete for any of the foregoing reasons, our business be restructured, or be materially harmed.

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The successful commercialization of completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may the exclusive right to commercialize any product candidate candidates we may develop, will depend in part on the extent could allow our competitors to w governmental authorities and health insurers establish adequate coverage, reimbursement levels, and pricing policies. Failure to obtain or maintain cover and adequate reimbursement for our product candidates, if approved, could limit our or our collaborators' ability bring products to market those products before we do, and decrease our or our collaborators' ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers, other third-party payors are essential for most patients to be able to afford prescription medications. Our ability to achieve acceptable levels of coverage and reimburs for products or procedures using our products by governmental authorities, private health insurers and other organizations will influence could impair our ability to successfully commercialize any product candidates we develop. Assuming may develop, any of which may harm our business, financial condition, results of operation prospects.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prev

Clinical trials of a new product candidate require the enrollment of a sufficient number of patients, including patients who are suffering from the disease the prc candidate is intended to treat and who meet other eligibility criteria. Rates of patient enrollment are affected by many factors, including the COVID-19 global endemic i similar events, the stage and severity of disease, the nature and requirements of the protocol, the proximity of patients to clinical sites, the availability of effective treat for the relevant disease, and the eligibility criteria for the clinical trial. Delays or difficulties in patient enrollment or difficulties retaining trial participants, including as a r of the availability of existing or other investigational treatments, can result in increased costs, longer development times or termination of a clinical trial.

Even if we complete the necessary preclinical studies and clinical trials, we cannot predict when, or if, we will obtain coverage regulatory approval to commercialize a product candidate and the approval may be for a narrower indication than we seek.

Prior to commercialization, any of our product candidates must be approved by the FDA pursuant to a new drug application, or NDA, in the United States and pursuant to similar marketing applications by the EMA and similar regulatory authorities outside the United States. The process of obtaining marketing approvals, both United States and abroad, is expensive and takes many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the ty complexity and novelty of the product candidates involved. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the prodct candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have no experience in submitting supporting the applications necessary to gain marketing approvals, and, in the event regulatory authorities indicate that we may submit such applications, we may be i to do so as quickly and efficiently as desired.

Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the prod manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderate effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining marketing approval or pre or limit commercial use. Regulatory authorities have substantial discretion in the approval process and may refuse to accept or file any application or may decide that data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and c testing could delay, limit or prevent marketing approval of a product candidate.

Approval of any of our product candidates may be delayed or refused for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- We may be unable to demonstrate, to the satisfaction of the FDA or comparable foreign regulatory authorities, that our product candidates are safe an any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approv
- We may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical programs or clinical trials;

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- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or procedures using our proc a other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the facilities of third-party payor, the resulting reimbursement payment rates manufacturers with which we contract or procure certain service or raw me not be adequate to support approval of our product candidates; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical

insufficient for approval.

Even if our product candidates meet their safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process.

Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or REMS. These regulatory authorities may require co-payments, precautions or contra-indications with respect to conditions of use or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates and adversely affect our business, financial condition, results of operations and prospects.

We may be unable to obtain regulatory approval in the United States or foreign jurisdictions and, as a result, be unable to commercialize our product candidates and our ability to generate revenue will be materially impaired.

Our product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, quality control, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs. Rigorous pre-clinical studies and clinical trials, and an extensive regulatory approval process are required to be successfully completed in the United States and in many foreign jurisdictions before a new drug can be marketed. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain, and subject to a continuously evolving regulatory environment and unanticipated delays. It is possible that none of the product candidates we may develop will obtain the regulatory approvals necessary for our collaborators to begin selling them.

The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending on the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when regulating companies such as ours are not always applied predictably or uniformly and can change. Any analysis we perform of data from chemistry, manufacturing and controls, preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays and increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be.

Any delay or failure in obtaining required approvals could adversely affect our ability to generate revenues from the particular product candidate for which we are seeking approval. Furthermore, any regulatory approval to market a product may be subject to limitations on the approved uses for which we may market the product, labeling or other restrictions. In addition, the FDA has the authority to require a REMS as a condition of approval, which may impose further requirements or restrictions on the distribution or safe use of an approved drug, such as limiting prescribing rights to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients **found unacceptable high**, as specially defined by the indication statement or who meet certain safe-use criteria, and requiring treated patients to enroll in a registry, among other requirements. These limitations and restrictions may limit the size of the market for the product and affect reimbursement by third-party payors.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and payment. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above, as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Approval by the FDA does not ensure approval by comparable regulatory authorities outside of the United States and vice versa.

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Any product candidate for which we obtain marketing approval will be subject to extensive post-marketing regulatory requirements and could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.

Our product candidates and the activities associated with their development and potential commercialization, including their testing, manufacturing, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other U.S. and international regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, including cGMPs, quality control, quality assurance and corresponding maintenance of records and documents, including periodic inspections by the FDA and other regulatory authorities and requirements regarding the distribution of samples to providers and recordkeeping.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of any approved product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with

provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products. If we promote our product candidates in a manner inconsistent with FDA-approved labeling or otherwise not in compliance with FDA regulations, we may be subject to enforcement action. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws and similar laws in international jurisdictions.

In addition, later discovery of previously unknown adverse events or other problems with our product candidates, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such product candidates, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of any approved product from the market;
- refusal to approve pending applications or supplements to approved applications that we may submit;
- recall of product candidates;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our product candidates;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the European Union's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Even if we obtain regulatory approvals, our marketed drugs will be subject to ongoing regulatory oversight. If we fail to comply with continuing U.S. and foreign requirements, our approvals, if obtained, could be limited or withdrawn, we could be subject to other penalties, and our business would be seriously harmed.

Following any initial regulatory approval of any drugs we may develop, we will also be subject to continuing regulatory oversight, including the review of adverse drug experiences and safety data that are reported after our drug products are made commercially available. This would include results from any post-marketing study or surveillance to monitor the safety and efficacy of the drug product required as a condition of approval or agreed to by us. Any regulatory approvals that we receive for

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our product candidates may also be subject to limitations on the approved uses for which the product may be marketed. Other ongoing regulatory requirements include, among other things, submissions of safety and other post-marketing information and reports, registration and listing, as well as continued maintenance of our marketing application, compliance with cGMP requirements and quality oversight, compliance with post-marketing commitments, and compliance with GCP for any clinical trials we conduct post-approval. Failure to comply with these requirements could result in warning or untitled letters, criminal or civil penalties, recalls, or product withdrawal. In addition, we intend to seek approval to market our product candidates in jurisdictions outside of the United States, and therefore will be subject to, and must comply with regulatory requirements in those jurisdictions.

The FDA has significant post-market authority, including, for example, the authority to require labeling changes based on new safety information and to require additional market studies or clinical trials for a variety of reasons. The FDA also has the authority to require a REMS plan after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug.

We, our CMOs, and the manufacturing facilities we use to make our product candidates will also be subject to ongoing assessment of product quality, compliance with cGMP, and periodic inspection by the FDA and potentially other regulatory agencies. We or our CMOs may not be able to comply with applicable cGMP regulations or similar regulatory requirements outside of the United States. Our failure, or the failure of our CMOs, to comply with applicable regulations could result in regulatory action such as the issuance of FDA Form 483 notices of observations, warning letters or sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, which could significantly and adversely affect supplies of our products. We may not have the ability or capacity to manufacture material at a broader commercial scale

future. We and our CMOs currently manufacture a limited supply of clinical trial materials. Reliance on CMOs entails risks to which we would not be subject if we manufactured all of the material ourselves, including reliance on the CMO for regulatory compliance. Our product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review.

If we or our collaborators, manufacturers or service providers fail to comply with applicable continuing regulatory requirements in the United States or foreign jurisdictions in which we may seek to market our products, we or they may be subject to, among other things, fines, warning letters, holds on clinical trials, refusal by the FDA or comparable foreign regulatory authorities to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, refusal to permit the import or export of products, operating restrictions, injunction, consent decree, civil penalties and criminal prosecution.

Any drugs we develop may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, thereby harming our business.

Because our product candidates represent new approaches to the treatment of genetic-based diseases, we cannot be sure that coverage and reimbursement will be available for, or accurately estimate the United States potential revenue from, our product candidates or elsewhere assure that coverage and reimbursement will be available for any product that we commercialize, and any reimbursement may develop. The regulations that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and the current presidential administration and Congress have introduced several proposals related to drug pricing. Many third-party payors may refuse to provide coverage govern marketing approvals, pricing and reimbursement for particular new drugs vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, pricing review period begins after marketing or biologics when an equivalent generic drug, biosimilar, or a less expensive therapy product licensing approval is available. Although there is no FDAP review period in the United States, in some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. We are monitoring these regulations as several of our programs move into later stages of development; however, many of our programs are currently not FDA-approved drugs in the earlier stages of development and we will not be able to assess the impact of price regulations for a number of years. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that could delay our commercial launch of the treatment product and negatively impact any potential revenues we may be able to generate from the sale of MS through the regeneration of myelin, it is possible product in that a third-party may consider country and potentially in other countries due to reference pricing. For more information, see Item 1 "Business – Government Regulation – No Uniform Framework Exists for Coverage and Reimbursement in the U.S." and "– Patients Rely on Insurance Coverage by Third-Party Payors (third-party payors include Medicare and Medicaid (government payors) and commercial insurance companies such as a drug as substitutable Blue Cross Blue Shield, Humana, Cigna, etc.) to Pay for Products."

Our ability to commercialize any products successfully will also depend in part on the extent to which coverage and only offer to reimburse patients adequate reimbursement/payment for the less expensive product. these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Even if we show improved efficacy, pricing of existing drugs succeed in bringing one or more products to the market, these products may limit not be considered medically necessary and/or cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. At this time, we will be unable to determine their cost effectiveness or the likely level or method of reimbursement for our product candidates. Increasingly, third-party payors, such as government and private insurance plans, are requiring that drug companies provide them with predetermined discounts from list prices, and are seeking to reduce the prices charged or the amounts paid for pharmaceutical products. If the price we are

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able to charge for any products we develop, or the payments provided for such products, is inadequate in light of our development and other costs, our return on investment could be adversely affected.

There may be significant delays in obtaining coverage for newly-approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or comparable foreign regulatory authorities. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to pay all or part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided and payment is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate payment is critical to product we commercialize. Payors acceptance. Coverage decisions may deny depend upon clinical and economic standards that disfavor new drug products when more established or revoke the reimbursement status of lower cost therapeutic alternatives are already available or subsequently become available. Moreover, eligibility for coverage does not imply that any drug will be paid for in all cases or at a given product or establish prices rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new or existing marketed products at levels that are too low to enable us to realize a satisfactory return on our investment in our product candidates. If reimbursement is not available or is available only at limited levels, we drugs, if applicable, may also not be able sufficient to successfully commercialize cover our product candidates costs and may not be able to obtain a satisfactory financial return on our product candidates. Additionally, our ability to obtain a satisfactory financial return depends on what, if any, proposals related to drug pricing made permanent. Reimbursement may be implemented based on payments allowed for lower-cost drugs that are already reimbursed, may be incorporated into existing payments for other services and if implemented, when may reflect

budgetary constraints or imperfections in Medicare data. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they might take effect.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models sold at lower prices than in the United States. Third-party payors often rely on Medicare coverage policy and payment limitations in setting their own reimbursement rates. However, no uniform policy requirement for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

No uniform policy for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor, and one third-party payor's decision to cover a product does not ensure that other payors will also provide similar coverage. Additionally, the process for determining whether a third-party payor will provide coverage for a product is typically separate from the process for setting the price of such product or establishing the reimbursement rate that the payor will pay for the product once coverage is approved. As a result, the coverage determination of coverage and reimbursement process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, our inability to promptly obtain coverage and regulations regarding adequate reimbursement change frequently, in some cases at short notice, rates from both government-funded and private payors for new drugs that we develop and for which we obtain regulatory approval could adversely affect our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

We believe that changes in these rules and regulations are likely.

Moreover, increasing the efforts by governmental agencies and third-party payors to contain or reduce the cost of healthcare and legislative and regulatory proposals to broaden the availability of healthcare will continue to affect the business and financial condition of pharmaceutical and biopharmaceutical companies. A number of legislative and regulatory changes in the healthcare system in the United States to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for any product we commercialize. We expect to experience pricing pressures in connection with the sale of any product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations, and additional legislative, administrative, or regulatory changes. The downward pressure on healthcare costs in general, particularly for prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. major healthcare markets have been proposed and/or adopted in recent years, and such efforts have expanded substantially in recent years. For more information on these changes, see Item 1 "Business—Governmental Regulation—Affordable Care Act and Legislative Reform Measures

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We may also not be subject to extensive governmental price controls and other market regulations outside of the United States, and we believe the increasing emphasis on cost-containment initiatives in other countries have and will continue to put pressure on the pricing and usage of medical products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulations could restrict the amount that we are able to charge obtain orphan drug exclusivity for products we commercialize. Accordingly, in markets outside the United States, the reimbursement for products we or commercialize may be reduced compared with the United States and may be insufficient to generate commensurate reasonable revenue and profits.

Even if a product candidate we develop receives marketing approval, it may fail to achieve market acceptance by physicians, patients, third-party payors, and others in the medical community necessary for commercial success.

If a product candidate we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community. For example, current MS treatments are well established in the medical community, and physicians may continue to rely on these treatments to the exclusion of ours. In addition, physicians, patients, and third-party payors may prefer other novel products to ours. If a product candidate does not achieve an adequate level of acceptance, we may not generate significant product revenues or become profitable. The degree of market acceptance of our product candidates, if approved, will depend on several factors, including, but not limited to:

- the efficacy and potential advantages compared to alternative treatments;
- effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our product together with other medications.

Because we expect sales of our product candidates, if approved, to generate substantially all our revenues for the foreseeable future, the failure of our product candidates to find market acceptance would harm our business and could require us to seek additional financing.

If we are unable to establish sales and marketing capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing any product candidate we develop, if approved.

In order to market and successfully commercialize any product candidate we develop, if approved, we must build our sales and marketing capabilities or enter collaborations with third parties for these services. We currently have no sales, marketing or distribution capabilities and as a company have no experience in marketing products. We intend to directly market and commercialize an MS therapeutic, if approved, by entering into collaborations for the sales and marketing of our product candidates, if approved. To the extent that we depend on collaborators for sales and marketing activities, any revenues we receive will depend upon the success of the collaborators' sales and marketing teams and the collaborators' prioritization of our product and compliance with applicable regulatory requirements, and there can be no assurance that the collaborators' efforts will be successful.

If we are unable to enter into a collaboration for the commercialization of product candidates we develop, if approved, we may be forced to delay the commercialization of our product candidates or reduce the scope of our sales or marketing activities, which would have an adverse effect on our business, operating results and prospects.

A variety of risks associated with operating internationally could materially adversely affect our business.

Our business strategy includes potentially expanding internationally if any of our product candidates receive regulatory approval. Doing business internationally involves several risks, including, but not limited to:

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- multiple, conflicting, and changing laws and regulations, such as data privacy and security laws and regulations, tax laws, export and import restriction sanctions laws and regulations, employment laws, regulatory requirements, and other governmental approvals, permits, and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors, or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and our products, and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade, and business restrictions;
- certain expenses, including, among others, expenses for travel, translation, and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, its books and records provisions, or its anti-bribery provisions, as well as other applicable laws and regulations prohibiting bribery and corruption.

Any of these factors could significantly harm any future international expansion and operations and, consequently, our results of operations.

Risks related to our dependence on third parties

We intend to continue to collaborate with third parties for the development and commercialization of any product candidates. We may not succeed in establishing and maintaining collaborations, which may significantly limit our ability to successfully develop and commercialize our other product candidates, if approved, at all.

We may seek collaborations for the development and commercialization of any product candidates. The process of establishing and maintaining collaborative relationships is difficult, time-consuming, and involves significant uncertainty, such as:

- a collaborator may shift its priorities and resources away from our product candidates due to a change in business strategies, or a merger, acquisition, downsizing;
- a collaborator may seek to renegotiate or terminate its relationships with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- a collaborator may cease development in therapeutic areas which are the subject of our collaboration;
- a collaborator may not devote sufficient capital or resources towards our product candidates, or may fail to comply with applicable regulatory requirements.

- a collaborator may change the success criteria for a product candidate, thereby delaying or ceasing development of such candidate;
- a significant delay in initiation of certain development activities by a collaborator will also delay payment of milestones tied to such activities, thereby in ability to fund our own activities;
- a collaborator could develop a product that competes, either directly or indirectly, with our product candidate;
- a collaborator with commercialization obligations may not commit sufficient financial resources or personnel to the marketing, distribution, or sale of a

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- a collaborator with manufacturing responsibilities may encounter regulatory, resource, or quality issues and be unable to meet demand requirements;
- a collaborator may terminate a strategic alliance;
- a dispute may arise between us and a collaborator concerning the research, development, or commercialization of a product candidate resulting in a d milestones or royalty payments or termination of the relationship and possibly resulting in costly litigation or arbitration, which may divert management and resources; and
- a collaborator may use our products or technology in such a way as to invite litigation from a third party.

If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development, manufacturing, or commercialization efforts r to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been t responsibility of our collaborator. If we are unable to establish and maintain collaborations on acceptable terms or to successfully transition away from terminated collaborations, we may have to delay or discontinue further development of one or more of our product candidates, undertake and even if we do, that exclusivity may r prevent the FDA or the EMA from approving other competing products.

Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug intended to treat a rare disease or condition. A similar regulatory scheme governs approval of orphan product candidates by the EMA in the EU. Generally, if a product with an orphan drug designation subsequently receive first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the from approving another marketing application for another product candidate for the same orphan therapeutic indication for that time period. The applicable period is se years in the United States and ten years in the EU. The exclusivity period in the EU can be reduced to six years if a product no longer meets the criteria for orphan designation, in particular if the product is sufficiently profitable so that market exclusivity is no longer justified.

The FDA's standards for granting orphan drug exclusivity in the gene therapy context are unclear and evolving. In order for the FDA to grant orphan drug excl to one of our product candidates, the agency must find that the product candidate is indicated for the treatment of a condition or disease that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product candidate available for the disease or condition will be recovered from sales of the product in the United States. The FDA may cor that the condition or disease for which we seek orphan drug exclusivity does not meet this standard. Even if we obtain orphan drug exclusivity for a product candidate, exclusivity may not effectively protect the product candidate from competition because different product candidates can be approved for the same condition. In addition even after an orphan drug is approved, the FDA can subsequently approve the same product candidate for the same condition if the FDA concludes that the later product candidate is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care compared with the product that has orphan exclusivity. Orphan drug exclusivity may also be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is u to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition.

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In August 2017, the Congress passed the FDA Reauthorization Act of 2017, or FDARA. FDARA, among other things, codified the FDA's pre-existing regulator interpretation, to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the se rare disease in order to receive orphan drug exclusivity. The new legislation reverses prior precedent holding that the Orphan Drug Act unambiguously requires that th recognize the orphan exclusivity period regardless of a showing of clinical superiority. The FDA may further reevaluate the Orphan Drug Act and its regulations and pc We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our bus Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

Our research, development and commercialization activities at manufacturing processes involve the use of hazardous materials. We maintain quantities of vari flammable and toxic chemicals in our own expense, facilities that are required for our research, development and manufacturing activities. We are subject to federal, s and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. Our procedures for storing, handling and disposing of these materials are reviewed against the relevant guidelines and laws of the jurisdictions in which our facilities are located on a regular basis. Although w believe that our safety procedures for handling and disposing of these materials sufficiently mitigate the risk of accidental contamination or find alternative sources inju

from these materials, the risk cannot be completely eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of capital, which would have a material adverse impact on biohazardous materials. Although we maintain workers' compensation insurance to cover costs and expenses we may incur due to injuries to our clinical development plans employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials. Additional federal, state and business local laws and regulations affecting our operations may become applicable in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violates any of, these laws or regulations.

If we or our collaborators, manufacturers, service providers or other third parties fail to comply with applicable healthcare laws and regulations, we could be subject to enforcement actions, which could affect our ability to develop, market and sell our products and may harm our reputation.

We are currently, or may in the future, be subject to federal, state, local, and comparable foreign healthcare laws and regulations relating to areas such as fraud and patients' rights. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our products for which we obtain marketing approval. For more information on these laws, see Item 1 "Business—Governmental Regulation—Other Healthcare Laws."

If our operations are found to be in violation of any such requirements, we may be subject to penalties, including civil or criminal penalties, criminal prosecution, monetary damages, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in federal healthcare programs including Medicare and Medicaid, the imposition of a corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services, disgorgement, individual imprisonment, contractual damages, reputational harm, and diminished profits and future earnings, any of which could adversely affect our financial results and adversely affect our ability to operate our business. We intend to develop and implement a comprehensive corporate compliance program prior to the commercialization of our product candidates. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses, could divert our management's attention from the operation of our business, and could harm our reputation, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

If we or our collaborators, manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could affect our ability to develop, market and sell our products successfully and could harm our reputation and lead to reduced acceptance of our products by the market. These enforcement actions include, among others:

- adverse regulatory inspection findings;
- warning and/or untitled letters;

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- voluntary or mandatory product recalls or public notification or medical product safety alerts to healthcare professionals;
- restrictions on, or prohibitions against, marketing our products;
- restrictions on, or prohibitions against, importation or exportation of our products;
- suspension of review or refusal to approve pending applications or supplements to approved applications;
- exclusion from participation in government-funded healthcare programs;
- exclusion from eligibility for the award of government contracts for our products;
- suspension or withdrawal of product approvals;
- product seizures;
- injunctions;
- consent decrees; and
- civil and criminal penalties, up to and including criminal prosecution resulting in fines, exclusion from healthcare reimbursement programs and imprisonment.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Moreover, federal, state or foreign laws or regulations are subject to change, and we, our collaborators, manufacturers and/or service providers currently may be compliant, that could change due to changes in interpretation, prevailing industry standards or other reasons.

Our employees, consultants and independent contractors, including principal investigators, CROs, consultants, vendors, and any third parties we may engage in connection with development and commercialization collaborators may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business requirements.

Our We are exposed to the risk of fraud and other misconduct by our employees, consultants and independent contractors, including principal investigators, CROs, consultants, vendors, collaborators. Such misconduct could include intentional failures to comply with FDA and any third parties we may engage in connection with agency regulations, provide accurate information to the FDA, comply with development manufacturing standards required by the FDA or us, comply with federal and commercialization of our product candidates, could engage in misconduct, including intentional, reckless, or negligent conduct or unauthorized activities that violate applicable laws, rules, state healthcare fraud and regulations including: the abuse laws and regulations, of the FDA or other similar regulatory requirements of other authorities, including those laws that require the reporting of true, complete, and accurate information to such authorities; manufacturing standards; data privacy, security, fraud and abuse, and other healthcare laws and regulations; or laws that require the reporting of true, complete, and accurate report financial information and data. Specifically, or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these or other laws Such misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter such misconduct, by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government agency could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, or them and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, and results of operations, including the imposition of significant civil, criminal, fines or other sanctions.

Product liability lawsuits against us could cause us to incur substantial liabilities and administrative penalties, damages, monetary fines, possible exclusion from participation could limit commercialization of any medicines that we may develop.

We face an inherent risk of product liability exposure related to the testing in Medicare, Medicaid, other U.S. federal healthcare programs human clinical trials of product candidates we may develop and will face an even greater risk if we commercially sell any medicines that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or healthcare programs in other jurisdictions, individual imprisonment, other sanctions, contractual damages, reputational harm or diminished profits medicines caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or medicines that we may develop;
- injury to our reputation and future earnings, and curtailment significant negative media attention;
- withdrawal of our operations;
- clinical trial participants;

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- significant time and costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any medicines that we may develop.

We currently intend anticipate that we will need to rely on third-party contract manufacturing organizations, increase our insurance coverage when we begin clinical trials and if we successfully commercialize any medicine. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Our internal computer and information systems, or those used by our CROs, CMOs for or other contractors or consultants, may fail or suffer security breaches which could result in a material disruption of our development programs.

Despite the production implementation of appropriate security measures, our internal computer and information systems and those of our current and any future CROs, CMOs and other contractors or consultants may become vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, telecommunications and electrical failures. While we have not experienced any such material system failure, or accident, and are unaware of any security breach to date, such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations.

whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of data from completed or future preclinical studies or clinical supply trials could result in significant delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the production further development and commercialization of commercial supply our product candidates could be significantly delayed.

We may be unable to adequately protect our information systems from cybersecurity incidents, which could result in the disclosure of confidential information, damage our reputation, and subject us to significant financial and legal exposure.

Cybersecurity incidents are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cybersecurity incidents include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, social engineering fraud or other means to threaten data confidentiality, integrity and availability. A cybersecurity incident could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. To date, we have not experienced a material compromise of our data or information system. However, although we devote resources to protect our information systems, we realize that cybersecurity incidents are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition.

Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidates outside the United States.

To market and sell our future product candidates as well as in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to supply raw materials necessary to obtain approval may differ substantially from that required to produce our product to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product candidate dependence on CMOs may impair reimbursement approvals before regulatory authorities will approve the development product for sale in that country. Failure to obtain foreign regulatory approvals or non-compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries.

If we fail to comply with the regulatory requirements in international markets and receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may impair not obtain foreign regulatory approvals on a timely basis, if at all. Our failure to obtain approval of any of our product candidates by regulatory authorities in another country may significantly diminish commercial prospects of that product candidate and our business prospects could decline.

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Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their commercialization, ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or modifications to approved drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

We, our collaborators and our service providers may be subject to a variety of privacy and data security laws, regulations and contractual obligations, and failure to comply with them could harm our business.

We maintain a large quantity of sensitive information, including confidential business and patient health information in connection with our preclinical studies, and are subject to laws and regulations governing the privacy and security of such information. In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal state security breach notification laws, and federal and state consumer protection laws. Each of these laws is subject to varying interpretations and new laws continue to be proposed. Outside of the United States, many jurisdictions have enacted stringent privacy and data protection laws. The collection, use, disclosure, transfer or other

processing of personal data originating from the European Economic Area, or EEA, and United Kingdom, or UK, is governed by the General Data Protection Regulation, or EU GDPR, and the UK General Data Protection Regulation, or UK GDPR, which, together with the EU GDPR, is referred to as the GDPR. For additional information on these regimes, see Item 1 "Business—Government Regulation—Privacy and Cybersecurity". Compliance with these and any other applicable privacy and data security regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms to ensure compliance, and despite those efforts we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our reputation, business, financial condition and results of operations.

The use of new and evolving technologies, such as artificial intelligence, or AI, in our offerings may result in spending material resources and presents risks and challenges that can impact our business including by posing security and financial position, other risks to our confidential information, proprietary information and personal information, and as a result we may be exposed to reputational harm and liability.

The use and integration of AI presents risks and challenges that could affect its adoption, and therefore our business. The use of certain artificial intelligence technology can give rise to intellectual property risks, including compromises to proprietary intellectual property and intellectual property infringement. Additionally, we expect to see increasing government and supranational regulation related to artificial intelligence use and ethics, which may also significantly increase the burden of research, development and compliance in this area. For example, the EU's Artificial Intelligence Act, or AI Act, is anticipated to enter into force in 2024 and, with some exceptions, become effective 24 months thereafter. This legislation imposes significant obligations on providers and deployers of high risk artificial intelligence systems and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. If we develop or deploy AI systems that are governed by the AI Act, we may be required to adopt higher standards of data quality, transparency, and human oversight, and adhere to standards that are potentially burdensome and costly ethical, accountability, and administrative requirements. The rapid evolution of AI will require the application of significant resources to help ensure that AI is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. Our vendors may in turn incorporate AI tools into their own offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

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Risks Related to Our Third Party Relationships

We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets of employees' or consultants' former employers or their clients. These claims may be costly to defend and if we do not successfully do so, we may be required to pay monetary damages and may lose valuable intellectual property rights or personnel.

Many of our employees were previously employed at universities or biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper our ability to commercialize, or prevent us from commercializing, our product candidates, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

We expect to rely on third parties to conduct our clinical trials and some aspects of our research, as well as some aspects of our delivery methods, and third parties may not perform satisfactorily, including failing to meet deadlines for manufacturing any product candidate. Instead, we rely on the completion of such trials, research or testing.

We currently, and expect to continue to, rely on CMOs third parties, such as CROs, clinical data management organizations, medical institutions, preclinical laboratories and clinical investigators, to conduct some aspects of our research. For example, we may rely on a third party to supply LNPs, or to conduct some of our preclinical animal experiments. Any of these third parties may terminate their engagements with us at any time under certain criteria. If we need to enter into alternative arrangements, we may delay our product development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibility. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the clinical trial. Moreover, the FDA, the EMA and other regulatory authorities require us and the study sites and investigators we work with to comply with standards, commonly referred to as GLPs and GCPs for conducting, recording and reporting the results of cGMP grade preclinical studies and clinical trials to assure, amongst other things, that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected.

We may not be successful in finding strategic collaborators for continuing development of any certain of our future product candidates we develop and, or successfully commercializing or competing in future, the market for commercial quantities. Reliance on CMOs may expose us to more risk than if we were manufacture our product candidates ourselves. If any CMO we engage is unable to provide sufficient supply of any product candidate we develop, certain indications.

In the future, we may be unable decide to arrange collaborate with non-profit organizations, universities, pharmaceutical and biotechnology companies for an alternative supply the development and potential commercialization of existing and new product candidates. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the de to do so on commercially reasonable terms or in a timely manner, which could delay any results of clinical trials, the commercial launch likelihood of our product candic if approved, or, regarding any commercial supply, result in a shortage in supply that could negatively impact our revenues.

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The facilities used to manufacture any product candidates we develop must be inspected approval by the FDA or similar regulatory authorities outside the Unit States, the potential market for the subject product candidate, the costs and comparable foreign regulatory authorities. While we provide oversight complexities of manufacturing activities, we do not and will not control delivering such product candidate to patients, the execution potential of manufacturing activities by, competing d the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and are industry and market conditions generally. The collaborator may also consider alternative product candidates or will technologies for similar indication may be dependent available to collaborate on our CMOs and whether such a collaboration could be more attractive than the one with us for compliance with cGMP requirements for the manufacture its product candidate. The terms of any product candidates. As a result, we are subject to the risk that any product candidates may f manufacturing defects additional collaborations or other arrangements that we may establish may not be favorable to us. Collaborations are complex and time-consum negotiate and document. In addition, there have limited ability to prevent. If been a CMO cannot successfully manufacture material significant number of recent busine combinations among large pharmaceutical companies that conforms to our specifications and the regulatory requirements, we will have resulted in a reduced number potential future collaborators.

We may not be able to secure or maintain regulatory approval for the use of our product candidates in clinical trials, or for commercial distribution of any produ candidates, if approved. We have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance, and qualified personnel, and we not involved in developing our CMOs' policies and procedures.

If the FDA or comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates withdraws any such approval or finds deficiencies in the future, we may need to find alternative manufacturing facilities, which would delay our development program i significantly impact our ability to develop, obtain regulatory approval for, or commercialize our product candidates, if approved. In addition, any failure to achieve and maintain compliance with laws, regulations, and standards related to manufacturing could subject us to risks, including the risk that we may have to suspend the manufacture of our product candidates, that obtained approvals could be revoked, and that the FDA or another governmental regulatory authority may take enforcement actions, including untitled letters, warning letters, seizures, injunctions, or product recalls. Furthermore, CMOs may breach existing agreements they have with us bec of factors beyond our control. They may also terminate or refuse to renew their agreement at a time that is costly or otherwise inconvenient for us. If we were unable to an adequate CMO or another acceptable solution in time, our clinical trials could be delayed, or our commercial activities could be harmed.

We contract for the supply of the active pharmaceutical ingredient, or API, and other raw material necessary to produce any product candidates we develop. Supplies of API or other raw material could be interrupted from time to time and we cannot be certain that alternative supplies could be obtained within a reasonable ti frame, at an acceptable cost, or at all. The extent to which the COVID-19 pandemic impacts our ability to procure sufficient supplies for the development of our produc product candidates will depend negotiate collaborations on the severity and duration of the spread of the virus, and the actions undertaken to mitigate the spread of C 19 or treat its effects and may cause delays. In addition, a disruption in the supply of API or other raw material could delay the commercial launch of our product candi if approved, or result in a shortage in supply, which would impair our ability to generate revenues. Growth in the costs and expenses of API or other raw material may impair our ability to cost-effectively manufacture our product candidates. In addition, there may be a limited number of suppliers for API or other raw material that we n use to manufacture our product candidates, and we cannot be certain that we will be able to engage such suppliers in a timely manner basis, on acceptable terms, or i If we are unable to do so, clinical we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay our produc candidates, development program or one or more of our other development programs, delay our potential commercialization for or reduce the scope of any approved product, sales or marketing activities, or increase our business could expenditures and undertake development or commercialization activities at our own expense. If w elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be advers affected, available to us on acceptable terms or at all. If we do not have

Finding new CMOs or third-party suppliers involves additional cost and requires our management's time and focus. In addition, there is typically a transition period w new CMO commences work. Although 73

sufficient funds, we have may not and do not intend to, begin a clinical trial unless we believe we have on hand, or will be able to obtain, a sufficient supply of our product candidates to complete the clinical trial, any significant delay in the supply of further develop our product candidates or bring them to market and generate product revenue.

The success of any potential collaboration arrangements will depend heavily on the raw materials needed to produce our product candidates, could consider a delay conducting our clinical trials efforts and potential regulatory approval activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidates, candidate and, in some cases, termination of such collaboration arrangements. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

As part of future acquisitions or strategic alliances could disrupt our business and harm our financial condition and results of their manufacture of our product candidates, our CMOs and third-party suppliers are expected to comply with and respect the proprietary rights of others. If a CMO or third-party supplier fails to acquire the proper licenses or otherwise infringes the proprietary rights of others in the course of providing services to us, we may have to find alternative CMOs or third-party suppliers or defend against claims of infringement, either of which would significantly impact our ability to develop, obtain regulatory approval for, or commercialize our product candidates, if approved.

operations.

We intend to may acquire additional businesses or drugs, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new drugs resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction. The risks we face in connection with acquisitions include:

- diversion of management time and focus from operating our business to addressing acquisition integration challenges;
- coordination of research and development efforts;
- retention of key employees from the acquired company;
- changes in relationships with strategic partners as a result of product acquisitions or strategic positioning resulting from the acquisition;
- cultural challenges associated with integrating employees from the acquired company into ours;
- the need to implement or improve controls, procedures, and policies at a business that prior to the acquisition may have lacked sufficiently effective controls, procedures and policies;
- liability for activities of the acquired company before the acquisition, including intellectual property infringement claims, violation of laws, commercial disputes, liabilities, and other known liabilities;
- unanticipated write-offs or charges; and
- litigation or other claims in connection with the acquired company, including claims from terminated employees, customers, former stockholders or other parties.

Our failure to address these risks or other problems encountered in connection with our past or future acquisitions or strategic alliances could cause us to fail to realize the anticipated benefits of these transactions, cause us to incur unanticipated liabilities and harm our business generally. There is also a risk that future acquisitions will result in the incurrence of debt, contingent liabilities, amortization expenses or incremental operating expenses, any of which could harm our financial condition or operations.

We rely, and anticipate that we will rely, on third parties to design, conduct, supervise and monitor our preclinical studies and clinical trials. If third parties do not successfully carry out their contractual duties, or if they perform in an unsatisfactory manner, it may harm our business.

We have relied, rely, and anticipate that we will continue to rely, on third party clinical investigators, CROs, CRO-contracted vendors, clinical data management organizations and clinical trial sites consultants to ensure the proper design, conduct, supervise and timely conduct of our clinical trials, including our planned Phase 1 in our MS Program, monitor preclinical studies and any future clinical trials of other our product candidates. Our reliance Because we rely on third parties and do not have the ability to conduct preclinical studies or clinical trials independently, we have less control over the timing, quality and other aspects of preclinical studies and clinical trials than we would if we conducted them on our own, including our inability to control whether sufficient resources are applied to our programs. If any of our CROs are acquired or consolidated, these concerns are likely to be exacerbated and our preclinical studies or clinical trials may be further impacted due to potential integration, streamlining staffing and logistical changes. These investigators,

CROs and consultants are not our employees and we have limited control over the amount of time and resources that they dedicate to our programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. Further, these parties may not be diligent, careful or timely in conducting our preclinical studies or clinical trial sites trials, resulting in the preclinical studies or clinical trials being delayed or unsuccessful.

If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not carry out their contractual duties, legal and regulatory requirements for the conduct of preclinical studies or clinical trials or meet expected deadlines, our preclinical and clinical development activities lie outside our control over these activities programs could be delayed and otherwise adversely affected. In all events, we were not involved in developing their policies and procedures but we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol general investigational plan and legal, regulatory, protocols for the trial. The FDA and scientific standards. For example, we have identified other health authorities require certain preclinical studies to be conducted in accordance with GLP, and corrected errors made by a clinical trials to be conducted in accordance with GCP, including conducting recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial site and a CRO in the FX-322-111 and FX-322-113 trials, respectively.

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We and our CROs will be required to comply with the Good Laboratory Practice requirements for our preclinical studies and GCP requirements for our clinical trials which participants are regulations and guidelines enforced by the FDA and are also required by comparable foreign regulatory authorities. Regulatory authorities enforce GCP requirements through periodic inspections of trial sponsors, principal investigators, and clinical trial sites. protected. If we or our CROs fail to comply with GCP the requirements, the clinical data generated in our clinical trials may be deemed unreliable or uninterpretable and the FDA or comparable foreign regulatory and other health authorities may require us to perform additional clinical trials. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. In the United States, we are also required to register certain clinical trials before approving and post the results of completed clinical trials on a government sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. Any such event could adversely affect our marketing applications, business, financial condition, results of operations and prospects.

We cannot assure you rely on third parties in the supply and manufacture of our product candidates for our research, preclinical and clinical activities, and do the same for commercial supplies of our product candidates.

We have not yet manufactured our product candidates on a commercial scale, and may not be able to do so for any of our product candidates. We currently rely on third parties in the supply and manufacture of materials for our research, preclinical and clinical activities and may continue to do so for the foreseeable future, including if we received regulatory approval for any product candidate. We may do the same for the commercial supply of our drug product. We use third parties to perform additional steps in the manufacturing process, such as the filling, finishing and labeling of vials and storage of our product candidates and we expect to do so for the foreseeable future. There can be no assurance that upon inspection our supply of research, preclinical and clinical development drug candidates and other materials will not be limited, interrupted or restricted or will be of satisfactory quality or continue to be available at acceptable prices. Replacement of any of the third parties we may engage could require significant effort and expertise because there may be a limited number of qualified replacements. In addition, raw materials, reagents, and components used in our manufacturing process, particularly those for which we have no other source or supplier, may not be available, may not be suitable or acceptable for use due to material component defects, or may introduce variability into the supply of our product candidates. Furthermore, with the increase of companies developing nucleic acid therapies, there may be increased competition for the supply of the raw materials that are necessary to make our oligonucleotides, which could severely impact the manufacturing of our product candidates.

We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and they must be acceptable to the FDA or approved by a given foreign regulatory authority, such as authorities. Suppliers and manufacturers, including us, must meet applicable manufacturing requirements including compliance with cGMP regulations, and undergo rigorous facility and process validation tests required by regulatory authority will determine authorities in order to comply with regulatory standards. In the event that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. Accordingly, if our CROs suppliers or manufacturers fail to comply with these such requirements or to perform their obligations in relation to quality, timing or otherwise, some of which may be out of their or our control, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be required forced to repeat clinical trials, increase the manufacturing of the materials ourselves, for which would delay the regulatory approval process.

Our CROs are not our employees, and we do not control whether they devote sufficient time currently have limited capabilities and resources, to our clinical trials. Our CROs may also have relationships or enter into an agreement with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities, another third party, which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reason, our clinical trials may be extended, delayed or terminated, and we may not be able to do so on reasonable terms, if at all. Any interruption of the development or operation of the manufacturing of our product candidates, such as order delays for equipment or materials, equipment malfunction, quality control and quality assurance issues, regulatory delays and possible negative effects of such delays on supply chains and expected timelines for product availability, production yield issues, shortages of qualified personnel, discontinuation of a facility,

or business or failure or damage to a facility resulting from natural disasters, could result in the cancellation of shipments, loss of product in the manufacturing process shortfall in available product candidates or materials. In some cases, the technical skills or technology required to manufacture our product candidates may be unique proprietary to the original manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or require us to obtain regulatory approval or successfully commercialize, any a license from such manufacturer in order to have another third party manufacture our product candidate that candidates. If we develop As a result, our financial results and the commercial prospects are required to change manufacturers for any product candidate reason, we will be required to verify the develop would be harmed, our costs the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could increase, and negatively affect our ability to generate revenue could be delayed. develop product candidates in a timely manner or within budget.

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We may also be required to enter into long-term manufacturing agreements that contain exclusivity provisions and/or substantial termination penalties which could have a material adverse effect on our business prior to or after commercialization of any of our product candidates. If our relationship with any CROs terminates, we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. While the COVID-19 pandemic and government measures taken in response have had a significant impact on our CROs and our ability to conduct clinical trials, there is potential they will face disruption in the future, which may affect our ability to initiate and complete our clinical trials. Though we try to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition, and prospects.

Risks related to healthcare laws and other legal compliance matters

Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of development and commercialize our product candidates if approved, and may affect the prices we may set.

In the United States and other jurisdictions, there have been, and we expect there will continue successfully. Failure to be, a number execute on our manufacturing requirements, either by us or by one of legislative and regulatory changes, and additional proposed changes, to the healthcare system that our third-party vendors, could adversely affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of health care. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the biotechnology and pharmaceutical industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and biologics that are infused, instilled, implanted, or injected;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with for such research; and
- establishment of a Center for Medicare and Medicaid Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

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Since its enactment, there have been judicial challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Trump issued an executive order initiating a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare. It is unclear how healthcare reform measures, if any, will impact our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In March 2021, the American Rescue Plan Act of 2021 was signed into law, which, among other things, eliminated the statutory cap on drug manufacturers' Medicaid Drug Rebate Program rebate liability, effective January 1, 2022. Under current law enacted as part of the ACA, drug manufacturers' Medicaid Drug Rebate Program rebate liability is capped at 100% of the average manufacturer price of a covered outpatient drug. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for our products.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been administration efforts, Congressional inquiries and proposed federal and state legislation designed to bring more transparency to drug pricing, reduce the cost of drugs, and increase competition.

prescription drugs under Medicare, review the relationship between pricing and manufacturer patient assistance programs and reform government program reimburse methodologies for drugs. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. Most recently, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated. We expect that additional U.S. federal healthcare reform measures will be implemented in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in increased demand for our product candidates or additional pricing pressures.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition, and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices. These reforms could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

In markets outside of the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Our business operations and current and future relationships with contractors, investigators, healthcare professionals, consultants, providers, physicians, third-party payors, patient organizations, customers, and others will be subject to applicable anti-kickback, fraud and abuse, anti-bribery and other healthcare regulatory laws and regulations, which could expose us to penalties, criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits and future earnings.

Our business operations Healthcare providers, physicians, and current third-party payors play a primary role in the recommendation and prescription of any product candidates that we may develop for which we obtain marketing approval. Our future arrangements with contractors, investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, manufacture, sell, and distribute our product candidates, if approved. Such laws include:

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- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in either the referral of an individual for, or the purchase, lease, order, or recommendation of, any good, facility, item or service, for which payment made, in whole or in part, we obtain marketing approval. Restrictions under U.S. applicable federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The U.S. federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, or healthcare providers on the other hand;
- the U.S. federal false claims, including the civil False Claims Act, or FCA, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. A claim includes "any request or demand" for money or property presented to the federal government. In addition, pharmaceutical manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of whether the program is public or private and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics, and medical devices;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where such reports are used in the calculation of reimbursement and/or discounts on approved products;
- the U.S. federal legislation commonly referred to as the Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations requires certain manufacturers of drugs, devices, biologics, and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse certified nurse anesthetists, anesthesiology assistants and certified nurse midwives) and teaching hospitals, as well as ownership and investment interests of such physicians and their immediate family members;
- analogous U.S. state laws and regulations including: state anti-kickback laws listed in the section above titled "Risks Related to Regulatory, Legal, and False Claims", including certain laws which may apply to our business practices, including but not limited to, research, distribution, sales, and marketing arrangements involving healthcare items or services reimbursed by any third-party payor, including private insurers; regulations applicable only if we have marketed products.

Some state laws that also require pharmaceutical companies to comply with the specific compliance standards, restrict financial interactions between pharmaceutical companies and the relevant compliance guidance promulgated by the U.S. federal government, and otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require pharmaceutical companies to file reports relating to pricing and marketing information, which requires tracking other remuneration and items of value provided to healthcare professionals and entities;

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- similar healthcare laws and regulations in the European Union, or EU, and other jurisdictions, including reporting requirements detailing interactions with healthcare providers; and
- laws and regulations prohibiting bribery and corruption such as the FCPA, which, among other things, prohibits U.S. companies and their employees from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to healthcare providers or their employees or agents, or to any foreign public official, foreign public officer, or foreign political party or official thereof.

Efforts to foreign government officials, employees of public international organizations or foreign government-owned or affiliated entities, candidates for foreign public office, and foreign political parties or officials thereof.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities, including our consulting agreements and other relationships with healthcare providers, some of whom receive stock or stock option compensation for their services, could be subject to challenge under one or more of such laws. Ensuring that our current and future internal operations and business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that given the breadth of the laws and regulations, limited guidance for certain laws and regulations and evolving government interpretations of the laws and regulations, governmental authorities will may possibly conclude that our business practices do may not comply with current or future statutes, regulations, agency guidance, or case law involving applicable fraud and abuse laws and other healthcare laws and regulations.

If our operations are found to be in violation of any of the laws described above or any other governmental laws and government regulations that may apply to us, we may be subject to actions penalties, including the imposition of civil, criminal, and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and other federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements, or oversight if we become subject to corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business, and our results of operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time consuming, and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against our business may be impaired.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, financial condition, results of operations, and financial condition prospects.

The global data protection landscape provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is rapidly evolving, prohibited in the EU. The provision of benefits or advantages to physicians is also governed by national anti-bribery laws of European Union Member States, such as the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization, and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Risks Related to Our Personnel, Operations and Growth

If we are unable to attract and retain qualified key management and scientists, staff, consultants and advisors, our ability to implement our business plan may be adversely affected.

We are highly dependent upon our senior management and our scientific, clinical and medical staff and advisors. The loss of the service of any of the members of our senior management or other key employees could delay our research and development programs and materially harm our business, financial condition, results of operations and prospects. In addition, we expect that we will continue to have an increased need to recruit and hire qualified personnel as we advance our programs and expand operations. Failure to successfully recruit and retain personnel could impact our anticipated development plans and timelines. For example, as a result of the COVID-19 pandemic, we have faced challenges in retaining and attracting employees to support our research and development efforts, and our failure to do so could have an adverse effect on our ability to execute on our business plan. We are dependent on the continued service of our technical personnel because of the highly technical and novel nature of our product candidates, platform and technologies and the specialized nature of the regulatory approval process. Replacing such personnel may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully execute our business strategy, and we cannot assure you that we will be able to identify or employ qualified personnel for any such position on acceptable terms, if at all. Many of the

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biotechnology and pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. Because our management team and key employees are not obligated to provide us with continued service, they could terminate their employment with us at any time without penalty. We do not maintain key person life insurance policies on any of our management team members or key employees. Our future success will depend in large part on our continued ability to attract and retain highly qualified scientific, technical and management personnel, as well as personnel with expertise in preclinical and clinical testing, manufacturing, governmental regulation and commercialization. In order to do so, we may become subject to the need to negotiate with state, federal and foreign governments for higher compensation or fees to our employees or consultants than we currently expect, and foreign laws, requirements and regulations governing private research institutions, government entities and other organizations. If we are unable to attract and retain qualified personnel, the collection, use, disclosure, retention, rate and security of our data, and our success at which we may be able to discover and develop our product candidates and implement our business plan will be limited.

We expect to expand our research, development, delivery, manufacturing, commercialization, regulatory and future sales and marketing capabilities over time, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of December 31, 2023, we had 101 full-time employees, including 34 who hold Ph.D. degrees, and one part-time employee; 74 employees are engaged in research and development and 27 employees in management or general and administrative activities. In connection with the growth and advancement of our pipeline and becoming a public company through the Merger, we expect to increase the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expected expansion of our operations or recruit and train additional qualified personnel. Moreover, our current physical laboratory space may be insufficient for our near-term research and development hiring plans, and the expected physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

As a growing biotechnology company, we are actively pursuing new platforms and product candidates in many therapeutic areas and across a wide range of diseases. Successfully developing product candidates for and fully understanding the regulatory and manufacturing pathways to all of these therapeutic areas and diseases requires a significant depth of talent, resources and corporate processes in order to allow simultaneous execution across multiple areas. Due to our limited resources, we may not be able to effectively manage this simultaneous execution and the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, legal or regulatory compliance failures, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects such as the development of our potential product candidates. If our management is unable to effectively manage the expected development and expansion of our operations, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to compete effectively and commercialize any product candidates we may develop will depend in part on our ability to effectively manage our future development and expansion.

Risks Related to Intellectual Property

If we are not able to obtain or protect intellectual property rights related to any of our product candidates, development and commercialization of our product candidates may be adversely affected.

In our industry, the majority of an innovative product's commercial value is usually realized during the period in which it has market exclusivity. Market exclusivity comprised of both patent and other intellectual property protection, as well as regulatory exclusivity. In the United States and some other countries, when market exclusivity expires and generic versions of a product are approved and marketed, there usually are very substantial and rapid declines in the product's sales. Accordingly, our success depends in part on our ability to obtain and maintain patents and other forms of intellectual property rights, including trademarks, trade secrets and, where necessary, licenses of intellectual property rights of others, in the United States and in other countries for our product candidates and platform technologies, as well as for methods used to manufacture our product candidates, and methods for treating patients for approved indications using our product candidates, as well as our ability to preserve trade secrets, to prevent third parties from infringing upon our proprietary rights and to operate without infringing upon the proprietary rights of others. Certain research and development activities involved in pharmaceutical development are exempt from patent infringement in the United States and other jurisdictions, for example, in the United States by the provisions

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of 35 U.S.C. § 271(1), or the Safe Harbor. However, in the United States and certain other jurisdictions, the Safe Harbor exemption can terminate when the sponsor submits an application for marketing approval (e.g., a New Drug Application, or NDA, in the United States). Therefore, the risk that a third party might allege patent infringement may increase as our product candidates approach commercialization.

We cannot offer any assurances about which of our patent applications will issue, the breadth of any resulting patent or whether any of the issued patents will be found invalid and unenforceable or will be threatened by third parties. We cannot offer any assurances that the breadth of our granted patents will be sufficient to stop a competitor from developing and commercializing a product. Furthermore, any successful challenge to these patents or any other patents owned by or licensed to us in the future after patent issuance could deprive us of rights necessary for the successful commercialization of any of our product candidates. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

We may not be able to apply for patents or obtain patent protection on certain aspects of our product candidates or our RNA editing platform OPERA in a timely fashion or at all. The patent prosecution process is expensive and time-consuming. We may not be able to prepare, file and prosecute all necessary or desirable patent applications at a commercially reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we may collect in connection with clinical trials fail to identify patentable aspects of inventions made in the U.S. course of development and abroad. Implementation standards commercialization activities before it is too late to obtain patent protection on them. We may not be able to obtain or maintain patent applications and enforcement practices patents due to the subject matter claimed in such patent applications and patents being in the public domain.

Our existing issued and granted patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technology. There is no guarantee that any of our pending patent applications will result in issued or granted patents, that any of our issued or granted patents will not later be found to be invalid or unenforceable, or that any issued or granted patents will include claims that are likely sufficiently broad to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, cover our product candidates, platform technologies, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to use any methods related to operate in certain jurisdictions, or to collect, store, transfer use provide meaningful protection from competitors. Consequently, it is unknown whether our platform technology or product candidates will be protectable or remain protected by valid and enforceable patents. Any failure to obtain, maintain or perceived failure by us to comply with federal, state or foreign laws or regulation, defend our internal policies, patents and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which other intellectual property could have a material adverse effect on our business financial conditions, results of operations financial performance and business prospects.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the U.S., HIPAA imposes, among other things, We cannot be certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. We may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. While we do not believe that we are currently acting as a the first to invent the inventions covered entity or business associate under HIPAA by pending patent applications and, thus if they are not, directly regulated under HIPAA, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances we could be subject to significant penalties if we violate HIPAA. Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potential complex compliance issues for us and our future customers and strategic partners.

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Further, we may also be or become subject to other state laws governing the privacy, processing and protection of personal information. For example, the California Consumer Privacy Act, or CCPA, went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and

security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states. Further, the California Privacy Rights Act, or CPRA, passed in California and it significantly amends the CCPA. It will impose additional protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and new rules for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions went into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Similar laws have passed in Virginia, Connecticut, Utah and Colorado, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA, or other domestic privacy and data protection laws, liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. For example, in Europe, the EU General Data Protection Regulation, or GDPR, went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States; in July 2020, the Court of Justice of the EU, or CJEU, limited how organizations could lawfully transfer personal data from the EU/EEA to the United States by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses, or SCCs. In March 2022, the US and EU announced a new regulatory regime intended to replace the invalidated regulations; however, this new EU-US Data Privacy Framework has not been implemented beyond an executive order signed by President Biden on October 7, 2022 on Enhancing Safeguards for United States Signals Intelligence Activities. European court and regulatory decisions subsequent to the CJEU decision of July 16, 2020 have taken a restrictive approach to international data transfers. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries in regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations and could adversely affect our financial results.

Further, from January 1, 2021, companies have had to comply with the GDPR and also the United Kingdom GDPR, or the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, and it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

We are subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.

Our operations, including our development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled

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use, handling, release, and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds, and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liabilities relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent, and we may be required to incur substantial expenses in connection with future environmental compliance, remediation activities, or litigation. We may be required to incur substantial expenses in connection with future environmental compliance, remediation activities, or litigation, in which case, the production efforts of our third-party manufacturers of certain patents or our development efforts of all of the term of certain patent applications. There may be interruptions or delays.

Risks related to our intellectual property

If prior art of which we are unable to obtain, maintain, enforce and protect not aware that may affect the validity or enforceability of a patent protection for our technology and product candidates or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates could be adversely affected.

Our success depends in large part on our ability to obtain and maintain protection prior art of the intellectual property we may own solely and jointly with others may license from others, particularly patents, in the United States and other countries with respect to any proprietary technology and product candidates we develop. seek to protect our proprietary position by filing patent applications in the United States and abroad related to our technologies and product candidates that are important to our business and by in-licensing intellectual property related to such technologies and product candidates. If which we are unable to obtain or maintain patent protection with respect to any proprietary technology or product candidate, our business, financial condition, results of operations and prospects could be materially harmed.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, defend, or license all necessary desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, aware, but which we do not have believe affects the right validity or enforceability of a claim, which may, nonetheless, ultimately be found to control affect the preparation, filing, and prosecution validity or enforceability of patent applications, or to maintain, enforce, and defend the patents, covering technology that we license from third parties. Therefore, these in-licensed patents, and applications may not be prepared, filed, prosecuted, maintained, defended, and enforced in a manner consistent with the best interests of our business.

The patent position of pharmaceutical and biotechnology companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the scope of patent protection outside of the United States is uncertain and laws of foreign countries may not provide our rights to the same extent as the laws of the United States or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. With respect to both owned and in-licensed patent rights, we cannot predict whether the patent applications we and our licensors currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors. Furthermore, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and claim. Because patent applications in the United States and other jurisdictions countries are typically not published for 18 months confidential for a period of time after filing, at any moment in time, we cannot be certain that we were in the past or will be in the future the first to file any patent application related to our product candidates. For example, some cases patent applications in the United States may be maintained in secrecy until the patents are issued. Furthermore, publications in the scientific literature often lag behind actual discoveries. Consequently, we cannot be certain that others have not published at all. Therefore, neither we nor our licensors can know with certainty whether either owned and issued patents or pending patent applications that we or, our licensors if applicable, a licensor were the first to make the inventions claimed in the patents and patent applications we own invent or in-license now or in the future, or that either we or our licensors were the first to file an application for the technology.

The patent protection position of such inventions, biotechnology and pharmaceutical companies can be highly uncertain and involves complex legal and factual questions. As a result, the issuance, scope, validity, enforceability and commercial value of our owned and in-licensed any patent rights are highly uncertain. Moreover, we will be able to protect our owned and in-licensed pending proprietary rights from unauthorized use by third parties only to the extent that our current and future patent applications may not result in patents being issued that protect our proprietary technology and product candidates are covered by valid and enforceable patents or are effectively maintained as trade secrets. If third parties disclose or misappropriate our proprietary rights, it may materially and adversely impact our position in the whole market.

It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in part, the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If there are material defects in the form, preparation, prosecution, maintenance or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

Legal issues related to the patentability of biopharmaceuticals, and methods of their manufacture and use, are complex and uncertain in some countries. In some countries, applicants are not able to protect methods of treating human beings or medical treatment processes. Intellectual property protection varies throughout the world and is subject to change over time. Certain jurisdictions have enacted various rules and laws precluding issuance of patents encompassing any methods a doctor may practice on a human being or any other animal to treat a disease or condition. Further, many countries have enacted laws and regulatory regimes that effectively prevent or not allow patent protection for methods of use of known compounds. Thus, in some countries and jurisdictions, it

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may not be possible to patent some of our product candidates at all. In some countries and jurisdictions, only composition claims may be obtained, and only when the compositions are or contain compounds that are new and/or novel. Also, patents issued with composition claims (i.e., covering product candidates) cannot always be enforced to protect methods of using those compositions to treat or diagnose diseases or medical conditions. Legal systems in certain countries may not favor enforcement or protection of patents, trade secrets and other intellectual property. Lack of intellectual property protection in such cases may have a materially adverse effect on our business and financial condition.

Furthermore, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates' manufacture or their use might expire before or shortly after those candidates receive regulatory approval and are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing competitive technologies products similar or identical to ours. We expect to seek extension of patent terms where these are available upon regulatory approval in those countries where we are prosecuting patents. This includes in the United States under the Dr

Price Competition and products. Changes in either Patent Term Restoration Act of 1984, which permits a patent term extension of up to five years beyond the patent expiration of the patent laws patent. However, the applicable authorities, including the FDA in the United States, and any equivalent regulatory authority in other countries, may diminish not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be possible.

The U.S. Patent and Trademark Office, or USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent prosecution process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, or loss of right to enforce patent claims, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. The standards applied by the USPTO and foreign patent offices granting patents are not uniform, can vary substantially from country to country, and are not always applied predictably, requiring country-specific patent expertise in a jurisdiction in which patent protection is sought. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology and pharmaceutical patents. As such, we do not know the degree of future protection that we will have on our product candidates and RNA editing technology. While we will endeavor to try to protect our product candidates and RNA editing technology with intellectual property rights such as patents, as appropriate in the process of filing and prosecuting patent applications, and obtaining, maintaining and defending patents is time-consuming, expensive, uncertain, and sometimes unpredictable.

Our pending patent applications may not issue as patents, and even issued patents may not provide sufficient protection of our RNA editing platform OPERA and our product candidates and issued patents may not provide.

In addition to claims directed toward the technology underlying our OPERA platform, our patents and patent applications contain claims directed to composition of matter on the active pharmaceutical ingredients, or APIs, in our product candidates, as well as methods-of-use directed to obtain, protect, maintain, defend, and enforce our patent rights, narrow the use of an API for a specified treatment. Composition-of-matter patents on the active pharmaceutical ingredient in prescription drug products provide protection without regard to any particular method of use of the API used. Method-of-use patents do not prevent a competitor or other third party from developing or marketing an identical product for an indication that is outside the scope of the patented method. Moreover, with respect to method-of-use patents, even if competitors or other third parties do not actively promote their product for our targeted indications or uses for which we may obtain patents, providers may recommend that patients use these products off-label, or patients may do so themselves. Although off-label use may infringe or contribute to the infringement of method-of-use patents, such practice is common and this type of infringement is difficult to prevent or prosecute.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or may in-license in the future may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. For example, while our patent protection and, more generally, could affect the value or narrow the scope of our patent rights.

Moreover, applications are pending, we or our licensors may be subject to a third-party pre-issuance third party preissuance submission of prior art to the United States Patent and Trademark Office, or USPTO or become involved in derivation proceedings, or equivalent proceedings in foreign jurisdictions.

Even if patents do successfully issue, third parties may challenge their inventorship, validity, enforceability or scope, including through opposition, derivation, revocation, reexamination, post-grant and inter partes review post-grant review, or interference proceedings challenging our patent rights or the patent rights of others, proceedings. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize our product candidates without infringing third-party patent rights. If the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome,

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it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Additionally, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if our owned and in-licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our owned and in-licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in our patent rights, loss of exclusivity, or freedom to operate or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial cost and require significant time from our management and employees. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. Moreover, our patents and patent applications may be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in patents or patent applications, such co-owners may be able to license their rights to other third parties,

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including our competitors, and our competitors could market competing products and technology. In addition, we may need the eventual outcome is favorable cooperation from any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Given the amount of breadth of time required for protection provided by the patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize our product candidates. Further, if we encounter delays in development, testing, and regulatory review of new product candidates, the period of time during which we could market our product candidates under patent protection would be reduced.

We may not identify relevant third-party patents protecting such candidates or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might expire before or shortly after such candidates are commercialized. Furthermore, adversely affect our competitors ability to develop and market our products.

Other parties have developed technologies that may be able related or competitive to circumvent our, and such parties may have filed or may file patent applications or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in our own patent applications or issued patents, with respect to either the same methods or formulations or the same subject matter, in either case, that we may rely upon to dominate our patent position in the market. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in owned or in-licensed patents by developing similar or alternative technologies pending patent applications, or products in a non-infringing manner, that we were first-to-file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our owned patent rights cannot be predicted with any certainty. Our competitors may have filed, and in-licensed may in the future file, patent portfolio applications covering our products or technology similar to our own. Any such patent application may not provide have priority over our patent applications or patents, which could require us with sufficient to obtain rights to exclude others from commercializing technology and products similar or identical to issued patents covering such technologies.

We cannot guarantee that any of our technology patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and product candidates.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In every third-party patent and pending application in the United States if all maintenance fees are timely paid, and abroad that relevant to or necessary for the natural expiration commercialization of our programs in any jurisdiction. The scope of a patent claim is generally 20 years from its earliest United States non-provisional filing date. Various extensions may be available, but determined by an interpretation of the life of law, the written disclosure in a patent and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once patent's prosecution history. Our interpretation of the relevance or the scope of a patent life has expired, or a pending application may be incorrect. For example, we may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be open incorrect. Our failure to competition from competitive products, including generics identify and correct interpret relevant patents may negatively impact our ability to develop and market our products. Moreover, we are also possible that prior art may exist that we are aware of but does not believe is relevant to our current or biosimilars. Given the amount of time required for the development, testing, and regulatory review of new product candidates, future patents, protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, but that could nevertheless determined to render our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, patents invalid.

We may be involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.

If Competitors may infringe the patents for which we are unable to obtain licenses from third parties on commercially reasonable terms have applied. To counter infringement or fail to comply with our obligations under such agreements, our business could be harmed.

It may be necessary for us to unauthorized use, the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales or an obligation or part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the technologies licensed to us.

If we are unable to obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and product candidates, which could significantly harm our business, financial condition, results of operations, and prospects.

Additionally, if we fail to comply with our obligations under license agreements, our counterparties may have the right to terminate these agreements, in which case we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely as

sublicense our rights under such agreements when it is in the interest of our business to do so, may result in our having to negotiate new or reinstated agreements with favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, or impede, or delay or prohibit further development or commercialization of, one or more product candidates that rely on such agreements.

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If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for any product candidates we may develop, our business may be materially harmed.

In the United States, the patent term of a patent that covers an FDA-approved drug may be eligible for limited patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. In addition, only one patent applicable to an approved drug may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions may be available in Europe and certain other non-United States jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, if and when our product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those product candidates, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted even if granted, the length of such extensions. We may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations, and prospects could be materially harmed.

It is possible that we will not obtain patent term extension under the Hatch-Waxman Act for a United States patent covering any of our product candidates that may identify even where that patent is eligible for patent term extension, or if we obtain such an extension, it may be for a shorter period than we had sought. Further, for licensed patents, we may not have the right to control prosecution, including filing with the USPTO, of a petition for patent term extension under the Hatch-Waxman Act. Thus, if one of our licensed patents is eligible for patent term extension under the Hatch-Waxman Act, we may not be able to control whether a petition to obtain a patent term extension is filed, or obtained, from the USPTO.

Also, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. We may be unable to obtain patents covering our product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If one of our product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviated new drug application filed with the FDA to obtain permission to sell a generic version of such product candidate.

Although we or our licensors are not currently involved in any litigation, we may become involved in lawsuits to protect or enforce our patent or other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors and other third parties may infringe, misappropriate or otherwise violate our or our licensors' issued patents or other intellectual property. As a result, we or our licensors may need to file infringement, misappropriation or other intellectual property related claims, which can be expensive and time-consuming. Any claims asserted against perceived infringers could provoke such parties to assert counterclaims against us alleging that we infringe, misappropriate, or otherwise violate their intellectual property. In addition, in enforcing a patent infringement proceeding, such parties covering one of our product candidates could counterclaim that the patents we patent covering our product or our licensors have asserted are invalid and/or unenforceable. Patent litigation in the United States, including counterclaims alleging invalidity and/or unenforceability, are commonplace, common, and there are numerous grounds on which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including for example, lack of novelty, lack of written disclosure, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal allegations of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products or certain aspects of our platform technology. Further, a court or administrative body could construe certain patent claims narrowly or refuse to prevent the other party from using the technology at issue on the ground that our patents do not cover the technology.

In an infringement proceeding, a court may decide that the patent claims we are asserting are invalid and/or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover the technology in question. Third parties may institute such also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., (for example, opposition proceedings)). Such proceedings could result in

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revocation of or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and possibly all, of the patent protection on our product candidates. An adverse result in any such proceeding litigation or defense proceedings could put one or more of our owned licensed patents at risk of being invalidated or interpreted narrowly, and could put any of our owned or in-licensed patent applications at risk of not yielding an issued patent. A court may also refuse to stop the third party from using the technology at issue in a proceeding on the grounds that our owned or in-licensed patents do not cover such technology. Furthermore, because of the substantial amount

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of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information or trade secrets issuing and could be compromised by disclosure during this type of litigation. Any of the foregoing could allow such third parties to develop and commercialize competing technologies and products and have a material adverse impact on our business, financial condition, results business. Such a loss of operations, patent protection could negatively impact business. Patents and prospects.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of invention with respect to other intellectual property rights also will not protect our technology if competitors design around our protected technology without legally infringing our patents or patent applications. other intellectual property rights.

An unfavorable outcome could require us to cease using the related technology or force us to attempt to take a license under the patent rights to it from of the prevailing party. Our party, if available. Furthermore, our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, all, or if a non-exclusive license is offered and our competitors gain access to the same technology, terms. Our defense of litigation or interference or derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, We may not be able to prevent misappropriation of our intellectual property rights, particularly in countries where the uncertainties associated with laws may not protect those rights as fully as in the United States.

Even if we establish infringement of any of our patents by a competitive product, a court may decide not to grant an injunction against further infringing activity allowing the competitive product to continue to be marketed by the competitor. It is difficult to obtain an injunction in U.S. litigation and a court could decide that the competitor should instead pay us a "reasonable royalty" as determined by the court, and/or other monetary damages. A reasonable royalty or other monetary damage or may not be an adequate remedy. Loss of exclusivity and/or competition from a related product would have a material adverse effect impact on our ability business.

If we in-licenses patent rights in the future, we may not have the right to raise file a lawsuit for infringement and may have to rely on a licensor to enforce these for us. If we are not able to directly assert our licensed patent rights against infringers or if a licensor does not vigorously prosecute any infringement claims on our behalf we may have difficulty competing in certain markets where such potential infringers conduct their business, and our commercialization efforts may suffer as a result.

In addition, we or our future licensors, as the funds necessary case may be, may not be able to continue detect infringement against our clinical trials, continue owned or in-licensed patents, which may be especially difficult for manufacturing processes or formulation patents. Even if we or our research programs, license necessary technology from future licensors detect infringement by a third parties, party of owned or enter into development partnerships future in-licensed patents, we licensors, as the case may be, may choose not to pursue litigation against or settlement with the third party. If we or our licensors later sue such third party for patent infringement, the third party may have certain legal defenses available to it that otherwise would help not be available but for the delay between when the infringement first detected and when the suit was brought. These legal defenses may make it impossible for us bring or our product candidates licensors to market.enforce owned or future in-licensed patents, as the case may be, against that third party.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other intellectual property proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

Third parties Third-party claims of intellectual property infringement may initiate legal proceedings alleging that we are infringing, misappropriating, preventing delay or otherwise violating their intellectual property rights, the outcome of which would be uncertain interfere with our product discovery and could have material adverse effect on the success of our business.development efforts.

Our commercial success depends upon in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technology without infringing, misappropriating or otherwise violating the intellectual property and/or proprietary rights of third parties.

There is considerable patent a substantial amount of litigation involving patents and other intellectual property litigation rights in the biotechnology and pharmaceutical and biotechnology industries. We may become party to, or threatened with, adversarial industries, as well as administrative proceedings or litigation regarding intellectual property rights with respect to our technology and product candidates, for challenging patents, including interference, proceedings, post grant review, derivation, inter partes review, post grant review, and derivation reexamination proceedings before the USPTO or oppositions and similar other comparable proceedings in foreign jurisdictions such as oppositions before the European Patent Office. jurisdictions. We may be exposed to, or threatened with, future litigation by parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights.

Numerous U.S. and foreign issued patents and pending patent applications which that are owned by third parties exist in the fields in which we are pursuing development developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our technologies or product candidates that we may identify may be subject give rise to claims of infringement of the patent rights of third parties. others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the number of patents issued and patent applications filed in our

The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings:

field, third parties may allege they have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. The risks of being involved in such litigation and proceedings may increase if and as patent rights encompassing our product candidates, near commercialization technologies or methods. We are a competitor in the oligonucleotide space whose patent application filings and/or issued patents may include claims directed to technologies and/or products related to some of our programs and as product candidates. For example, we gain the greater visibility associated with being a public company. Third parties are aware of patents and patent applications owned by third parties may assert infringement that have generic claims against us based on existing patents or patents that may be granted in the future regardless of merit. We may not be aware of all such intellectual property rights potentially relating relate to our technology technologies and product candidates and their uses, or we may incorrectly conclude that products.

If a third party intellectual property is invalid or claims that our activities and product candidates do not infringe such intellectual property. Thus, we do not know with certainty that our technology and product candidates, or our development and commercialization thereof, do not and will not infringe, misappropriate or otherwise violate third party's our intellectual property. property rights, we may face a number of issues, including, but not limited to:

Third parties may assert infringement and other intellectual property claims that, we are employing their proprietary technology without authorization. There regardless of merit, third party patents or patent applications with claims expensive and time-consuming to materials, formulations, methods of manufacture or methods litigate against our management's attention from our core business;

- substantial damages for treatment related to the discovery, use or manufacture of the product candidates that infringement, which we may identify or rely on our technologies. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in patents that pay if a court decides that the product candidates candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds the infringement was willful, we may develop may could be found ordered to infringe. In addition, third parties may obtain patents in pay treble damages in the future and claim that use of our technologies infringes upon these patents. Moreover, as noted above, there may be existing patents that we are not aware of that we have incorrectly concluded are invalid or not infringed by our activities. If any third-party patents were held by patent owner's attorneys' fees;
- a court of competent jurisdiction to cover, for example, the prohibiting us from developing, manufacturing, process of the marketing or selling our product candidates that we may develop, any molecules formed during or from using our proprietary technologies, unless the manufacturing process third party licenses its rights to us, which it is not required to do, on commercially reasonable terms or any final product itself, the holders of any such patents may be able to prevent us from commercializing such product candidate unless we obtained at all;
- if a license under the applicable patents, or until such patents expire.

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Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize the product candidates that we may identify. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would result in a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, third party, we may be required to pay substantial damages, including treble damages royalties, upfront fees and attorneys' fees for willful infringement, pay royalties, redesign our infringing product, or other amounts, and/or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may choose to grant cross-licenses to take a license or, if we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights for our product candidates;

- the requirement that we could also be required to obtain a license from such third party to continue developing, manufacturing and marketing our technologies.

product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing technology or product. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, for infringing technology or product. In addition, we could be forced to indemnify our customers or collaborators. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, processes so they do not which could materially harm our business. In addition, we may not be forced to redesign our product candidates, seek new regulatory approvals, possibly require substantial monetary expenditures and indemnify third parties pursuant to contractual agreements. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations, time; prospects.

- Intellectual property litigation or other legal proceedings relating to intellectual property could cause us to spend substantial resources and distract our personnel from their normal responsibilities.** Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments that we perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such increase in our operating losses and reduce the resources available for development activities or any future sales, mark have sufficient financial or other resources to conduct such litigation or proceedings adequately.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, financial condition, results of operations and prospects.

Third parties may assert that we are employing their proprietary technology without authorization, including by enforcing its patents against us by filing a patent infringement lawsuit against us. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof.

There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of its product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents.

If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, or materials used in or for the manufacturing process, or any final product itself, the holders of those patents may be able to block our ability to commercialize our product candidate unless we obtain a license under the applicable patents, or until those patents were to expire or those patents are finally determined to be invalid or unenforceable. Similarly, if a third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of that patent may be able to block our ability to develop and commercialize the product candidate unless we obtain a license or until such patent expires or is finally determined to be invalid or unenforceable. In either case, a license may not be available on commercially reasonable terms or at all, particularly if such patent is owned or controlled by one of our primary competitors. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could significantly harm our business. If we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to it. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee time and resources from our business. In

the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement. We may be required to obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any license of this nature would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates and may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could significantly harm our business.

Likewise, our patents and patent applications, if issued as patents, directed to our proprietary technologies and our product candidates are expected to expire 2040 through 2044, without taking into account any possible patent term adjustments or extensions. Our earliest in-licensed patents may expire before, or soon after, our first product achieves marketing approval in the United States or foreign jurisdictions. Additionally, we cannot be assured that the USPTO or relevant foreign patent office will grant any of the pending patent applications we own or in-license currently or in the future. Upon the expiration of our current patents, we may lose the right to exclude others from practicing these inventions. The expiration of these patents could also have a similar material adverse effect on our business, financial condition, results of operations and prospects.

We or our future licensors, collaborators or strategic partners may be subject to third-party claims for infringement or misappropriation of patent or other proprietary rights. We may be generally obligated under our future potential license or collaboration agreements to indemnify and hold harmless our licensors or collaborators for damages arising from intellectual property infringement by us. If we or our future licensors, collaborators or strategic partners are found to infringe a third-party patent or other intellectual property rights, we could be required to pay damages, potentially including treble damages, if we are found to have willfully infringed. In addition, our future licensors, collaborators or strategic partners may choose to seek, or be required to seek, a license from a third party, which may not be available on acceptable terms, if at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to it. If we fail to obtain a required license, we or our future collaborators may be unable to effectively market product candidates based on our technology, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. In addition, we may find it necessary to pursue claims or initiate lawsuits to protect or enforce our patent or other intellectual property rights. The cost to us of defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation could divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations.

Additionally, we may be required to protect our patents through procedures created to attack the validity of a patent at the USPTO. An adverse determination in such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. Because a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

We may not be successful in acquiring or in-licensing necessary rights to key technologies or any product candidates we may develop.

The future growth of our business may depend in part on our ability to in-license or otherwise acquire the rights to additional product candidates and technologies. There has been extensive patenting activity in the field of gene editing. Pharmaceutical companies, biotechnology companies and academic institutions are competing with us or are expected to compete with us in the field of gene editing technology and filing patent applications potentially relevant to our business. In order to market our product candidates, we may find it necessary or prudent to obtain licenses from third-party intellectual property holders. However, we may be unable to secure such licenses or otherwise acquire or in-license any compositions, methods of use, processes, or other intellectual property rights from third parties that we identify as necessary to develop or commercialize our product candidates or other key technologies. We may also require licenses from third parties for certain additional technologies, including technologies relating to RNA editing, such as guide RNA modification, or target sequences as well as delivery technologies for product candidates we may develop. We may not be able to obtain such a license on an exclusive basis, on commercially reasonable terms, or at all, which could prevent us from commercializing our product candidates or allow our competitors or other third parties the chance to access technology that is important to our business.

Additionally, we may collaborate with academic institutions to accelerate our research or development under written agreements with these institutions. In certain cases, these institutions may provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Even if we exercise such an option, we may be unable to

negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, such institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program.

The licensing or acquisition of third-party intellectual property rights is a highly competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that it may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all.

It is possible that we may be unable to obtain required licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, programs, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected programs, which could harm our business, financial condition, results of operations, and prospects significantly.

Disputes may arise between us and our future licensors regarding intellectual property subject to a license agreement, including: the scope of rights granted under the license agreement and other interpretation-related issues; whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; our right to sublicense patents and other rights to third parties; our right to transfer or assign the license; the inventorship ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners; and the priority of invention of patented technology.

If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issued thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our programs or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees.

Our future licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we have licensed. If other third parties have ownership rights or other rights to our licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Third parties may assert that our employees, consultants, or advisors have wrongfully used or disclosed confidential information or misappropriated trade secrets.

As is common in the biotechnology and pharmaceutical industries, we employ individuals that are currently or were previously employed at universities, research institutions or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Also, we have in the past and may in the future be subject to claims that these individuals are violating non-compete agreements with their former employers. We may have to pursue litigation to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our technical management personnel from their normal responsibilities. In addition,

there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, that perception could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities, and we may not have sufficient financial or other resources adequately conduct this type of litigation or proceedings. For example, some of our competitors may be able to sustain the costs of this type of litigation or proceeding effectively than we can because of their substantially greater financial resources and may also have an advantage in such proceedings due to their more mature and developed intellectual property portfolios. Uncertainties resources. In any case, uncertainties resulting from the initiation and continuation of intellectual property litigation other intellectual property related proceedings could compromise adversely affect our ability to compete in the marketplace.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental government patent agencies, and our patent protection could be reduced or eliminated for noncompliance non-compliance with requirements.

Periodic maintenance fees, renewal and fees, annuity fees, and various other government fees on any issued patent patents and pending patent application must applications are due to be paid to the USPTO and foreign patent agencies in several stages or annually outside of the United States over the lifetime of our owned in-licensed or licensed patents and patent applications. The USPTO and various foreign governmental patent agencies require compliance with a number of several procedural, documentary, fee payment, and other similar provisions during the patent application process. In certain circumstances, we rely We are also dependent on licensing partners licensors to pay these fees take the necessary action to or comply with the procedural and documentary rules of, the relevant patent agency. With the requirements with respect to our patents, we rely on an annuity service, outside firms, and outside counsel to remind us of the due dates and to make payment after we instruct them to do so. licensed intellectual property. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations, however, in which noncompliance non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of Were a patent or patent application include failure noncompliance event to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. Under certain circumstances, we may be unable to comply with requirements. For example, due to the sanctions imposed by the United States on Russia as a result of the conflict in Ukraine, it is not possible to pay fees on Russian patents and the future of such patents is uncertain. In such an event, potential our competitors might be able to enter the market with similar or identical products or technology. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, it would have a material adverse effect on our business, financial condition, results of operations, and prospects.

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Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of patent laws in the United States, including patent reform legislation such as the Leahy-Smith America Invents Act, or the Leahy-Smith Act, could increase the uncertainties and costs surrounding the prosecution of our owned and in-licensed patent applications and the maintenance, enforcement, or defense of our owned and in-licensed issued patents. The Leahy-Smith Act includes a number of significant changes to United States patent law. The changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution, and additional procedures to attack the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding prosecution of our patent applications and the enforcement or defense of our issued patents, all of technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. A combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property and proprietary rights throughout the world.

We have limited intellectual property rights outside the United States. Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, and even where such protection is nominally available, judicial and governmental enforcement of such rights is not always effective. In addition, our intellectual property rights licenses agreements may be lacking. not always include worldwide rights. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our

technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection or licenses, but where enforcement is not as strong as that in the United States. These products may compete with our products, product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology and pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products by third parties in violation of our intellectual property and proprietary rights generally. In addition, certain jurisdictions do not protect, to the same extent or at all, inventions that constitute new methods of treatment.

In addition, geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensees. For example, the United States and foreign government actions related to Russia's conflict in Ukraine may limit or prevent filing, prosecution, and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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Proceedings to enforce our patents and intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Moreover, the initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

Finally, Europe is implementing a Unified Patent Court that

Further, filing, prosecuting and defending patents on programs worldwide would be prohibitively expensive and our intellectual property rights in some foreign jurisdictions can be less extensive than those in the United States. As such, we may present uncertainties not have patents in all countries or all major markets and may not be able to obtain patents in all jurisdictions even if we apply for them. Our competitors may operate in countries where we do not have patent protection and can freely use our technologies and discoveries in such countries to the extent such technologies and discoveries are publicly known or disclosed in countries where we do have patent protection or pending patent applications.

Changes in patent law in the United States and in non-U.S. jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our RNA editing platform technology and enforce product candidates.

As is the case with other biotech and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain.

Changes in either the patent laws or interpretation of the patent laws could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of our issued patents and pending patent applications. For example, in March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, the United States transitioned from a "first to invent" to a "first-to-file" patent system. Under a "first-to-file" system, assuming that other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on an invention regardless of whether another inventor had made the invention earlier. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application.

Because patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either file any patent application related to our technology or product candidates or invent any of the inventions claimed in our or our licensors' patents or patent applications. The America Invents Act also includes a number of other significant changes to U.S. patent law, including provisions that affect how patent applications are prosecuted, allowing third party submission of prior art and establishing a post-grant review system including post-grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal court proceedings necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent rights claims that would not have been invalidated if first challenged by the third party as a defendant in Europe a district court action.

In addition, recent U.S. Supreme Court and the ability U.S. Court of third parties to do the same. In 2012, regulations were passed with the goal of providing a European Unitary Patent and a new European Unified Patent Court, or UPC, for litigation involving European patents. Implementation is currently scheduled for June 2023. Under the UPC, all European patents granted in countries that have ratified the UPC Agreement, including those patents issued prior to the UPC, will automatically fall under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke European patents, and allow Appeals for the possibility of a competitor to obtain injunctions in multiple European countries in a single UPC action. It will be several years before we will understand Federal Circuit rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights that will be recognized of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, these rulings have created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the strength of patent remedies USPTO, the laws and regulations governing patents could change in unpredictable ways that will be provided could weaken our ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future. We cannot predict how future decisions by the UPC. Note that we will have courts, the option to opt our patents out of U.S. Congress or the UPC over the first seven years of the court's existence, but doing so USPTO may preclude us from realizing the benefits of the new unified court. **If we fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.**

We are party to license and funding agreements that impose, and we may enter into additional licensing and funding arrangements with third parties that may impose, diligence, development, and commercialization timelines, milestone payment, royalty, insurance and other obligations on us. Under our existing licensing and funding agreements, we are obligated to pay royalties on net product sales of product candidates or related technologies to the extent they are covered by the agreements. If we fail to comply with such obligations under current or future license and funding agreements, our counterparties may have the right to terminate these agreements and require us to grant them certain rights. Such an occurrence could materially adversely affect impact the value of any product candidate being developed under any such agreement. Termination of our patents. Any adverse changes in the patent laws of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, which would other jurisdictions could also have a material adverse effect on our business, financial condition, results of operations and prospects.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- Geopolitical actions in the scope of rights granted under United States and in foreign countries could increase the license agreement uncertainties and interpretation related issues;
- costs surrounding the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing prosecution or maintenance of patent applications and other the maintenance, enforcement or defense of issued patents. For example, the United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of patent applications, resulting in partial or complete loss of patent rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in Russian law such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have their primary place of business in, the United States. This decree could have a material adverse effect on our business, financial condition, results of operations, and prospects.

or profit-making activities in the United States and prospects. Moreover, if disputes over intellectual property arise in other countries that Russia has deemed unfriendly without our consent or compensation. Consequently, we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms. If we are unable to successfully develop and commercialize the affected technology and product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

Our current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are would not be and exclusive owners of the patents and patent applications we in-license. If other third parties have ownership rights to patents and/or patent applications we in-license they may be able to license such patents to prevent third parties from practicing our competitors, inventions in Russia or from selling or importing products made using inventions in and our competitors could market competing products and technology. This could have a material adverse effect on into Russia. Accordingly, our competitive position, business, financial conditions, results of operations, and prospects.

In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize product candidates and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying intellectual property fails to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products and technologies identical to ours. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

We may be subject to claims challenging the inventorship or ownership of our patents impaired, and other intellectual property.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations to employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets, or other intellectual property. If we or our licensors fail in defending against such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. Prospects may be adversely affected.

In addition, recently the European Unified Patent Court, or UPC, was created as a common patent court to hear patent infringement and revocation proceedings effective for member states of the EU. This could enable third parties to seek revocation

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of a European patent in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated. Although we do not currently own any European patents or applications, if we obtain such patents and applications in the future, any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Moreover, the controlling law and regulations of the UPC will develop over time, and may adversely affect our ability to enforce or defend the validity of any European patents we may obtain. We may decide to opt out from the UPC any future European patent applications that we may file and any patents we may obtain. If certain formalities and requirements are not met, however, such European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. We cannot be certain that future European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we also rely on know-how and trade secrets and secret protection, as well as confidentiality agreements, non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our unpatented know-how, technology, confidential and other proprietary information, especially where we do not believe patent protection is appropriate or obtainable.

It is our policy to maintain our competitive position. We seek to protect our trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as require our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties. We also enter into parties to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed by or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and invention not disclosed to third parties, except in certain specified circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and that are related to our current or patent assignment planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information are our exclusive property. In the case of consultants and other third parties, the agreements provide that all inventions conceived in connection with the services provided are our employees and consultants. We exclusive property. However, we cannot guarantee that we have entered into such agreements with each party that may have had access to our trade secrets or proprietary technology. Despite these efforts, any technology and processes. Additionally, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Detecting the disclosure or misappropriation of a trade secret and enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information through other appropriate precautions, such as physical and technological security measures. However, trade secrets and know-how can be difficult to protect. These measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and any recourse we might take against this misconduct may not provide an adequate remedy to protect our interests fully. In addition, trade secrets may be independently developed by others in a manner that could prevent us from receiving legal recourse. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if that information was independently developed by a competitor, our competitive position could be harmed.

In addition, some courts inside and outside of the United States are sometimes less willing or unwilling to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. Even if we are successful, these types of lawsuits may consume our time and other resources. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Patent terms may be inadequate to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed or independently developed by a competitor or other third party, protect our competitive position would on our product candidates for an adequate amount of time.

Patents have a limited lifespan. The terms of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest non-provisional filing date in applicable country. However, the actual protection afforded by a patent varies from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. Various extensions including PTE and PTA, may be materially available, but the life of a patent, and adversely harmed, the protection it affords, is limited. For more information regarding PTA and PTE, see Item 1 "Business—Intellectual Property". Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics. Given the amount of time required for the development,

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testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after we or our partners commercialize those candidates. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar to ours.

If our trademarks we do not obtain PTE and trade names are not adequately protected, then data exclusivity for any product candidates we may not be able to build name recognition in our markets of interest and develop, our business may be adversely affected, materially harmed.

Our registered trademarks Depending upon the timing, duration and unregistered trademarks specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be challenged, infringed, circumvented, eligible for limited PTE under the Drug Price Competition and Patent Term Restoration Act of 1984, or declared generic the Hatch-Waxman Amendments. The Hatch-Waxman Amendments PTE term of up to five years as compensation for patent term lost during the FDA regulatory review process. A PTE cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent per product may be extended and only those claims covering the approved drug, a method for using it, or a determined method for manufacturing it may be extended. However, even if we were to be infringing on other marks. We seek a PTE, it may not be able granted because of, for example, the failure to protect rights exercise due diligence during the testing phase or regulatory review process, the failure to these trademarks and trade names, which we need apply within applicable deadlines, the failure to build name recognition among potential collaborators apply prior to expiration of relevant patents, or customers in our markets any other failure satisfy applicable requirements. Moreover, the applicable time period or the scope of interest. At times, competitors may adopt trade names or trademarks similar to ours thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, the patent protection afforded could be potential trade name trademark infringement claims brought by owners of other registered trade names or trademarks that incorporate variations of our unregistered trade names or trademarks. Over the long term, if less than we request. If we are unable to successfully register obtain PTE or term of any such extension is less than we request, our trade names, trademarks and establish name recognition based on competitors may obtain approval of competing products following our trade names and trademarks, then we may be able to compete effectively, patent expiration, and our business, may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks and trademarks may

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be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition, or results of operations, and prospects could be materially harmed.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- any product candidates we may develop will eventually become commercially available in generic or biosimilar product forms;
- others may be able to make gene therapy products that are similar to any product candidates we may develop or utilize similar base editing technology not covered by the claims of the patents that we may own in the future;
- We, or our future license partners or current collaborators, might not have been the first to make the inventions covered by the issued patent or pending application that we license or may own in the future;
- We, or our future license partners or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- We, or our future license partners or collaborators, may fail to meet our obligations to the U.S. government regarding any in-licensed patents and patents funded by U.S. government grants, leading to the loss or unenforceability of patent rights;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or in-licensed intellectual property rights;
- it is possible that our owned and in-licensed pending patent applications or those that we may own or in-license in the future will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate our patents, or parts of our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our product technology similar to ours;
- it is possible that our patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- issued patents that we hold rights to may be held invalid, unenforceable, or unenforceable, narrowed in scope, including as a result of legal challenges from competitors;
- the claims of our issued patents or patent applications, if and when issued, may not cover our product candidates;

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- the laws of foreign countries may not protect our proprietary rights or the proprietary rights of our future license partners or collaborators to the same extent as the laws of the United States;
- the inventors of our patents or patent applications may become involved with competitors, develop products or processes that design around our patents, or be named as inventors on patents or patent applications on which they are named as inventors;
- our competitors might may conduct research and development activities in countries where we do not have patent rights or enforceable patent rights and may use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we cannot ensure we have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent competing products that any are outside the scope of our pending patent applications, if issued, or those of our licensors, will include claims having a scope that may overlap with or be broader than the claims of our patents or patent applications to protect our product candidates;
- we cannot ensure that any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable product candidates and will provide us with any competitive advantages;
- we cannot ensure that our commercial activities or product candidates will not infringe upon the patents of others;
- we cannot ensure that we will be able to successfully commercialize our product candidates on a substantial scale, if approved, before the relevant patents expire, or our license expires;
- we may not develop additional proprietary technologies that are patentable;
- any product candidates we develop may be covered by third parties' patents or other exclusive rights;
- a third party may challenge, invalidate, circumvent or weaken our patents, and as a result, a court could hold that our patents are not valid, enforceable or not infringed;
- the patents of others may harm our business; and or
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering our technology or product.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks related to our employees, managing our growth and our operations

Our future success depends use of open source software could impose limitations on our ability to retain commercialize our key personnel and to attract, and motivate qualified personnel, product candidates.

We are highly dependent Our use of open source software could impose limitations on the expertise of David L. Lucchino, our President and Chief Executive Officer, as well as the other principal members of our management, scientific, and clinical teams. Although we have employment agreements, offer letters or consulting agreements with our executive officers, these agreements do not prevent them from terminating their services at any time.

If we lose one or more of our executive officers or key employees, our ability to implement commercialize our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers and key employees product candidates. Our technology utilizes open source software that contains modules license use from third-party authors under open source licenses. In particular, some of the software that powers OPERA may be difficult and may take an extended period because provided under license arrangements that allow use of the limited number of individuals software for research or other non-commercial purposes. As a result, future, as we seek to use our industry platform in connection with the breadth of skills and experience required to develop, gain regulatory approval of and commercial product candidates successfully. Competition to hire from this limited pool is intense, and commercially available products, we may be unable required to hire, train, retain and motivate these additional key personnel on acceptable license that software under different license terms, given the competition among numerous biotechnology and pharmaceutical companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. We may also decide not to replace an executive officer, which may have an adverse effect not be possible on our operations. For

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example, we do not have a Chief Financial Officer and do not currently intend to fill that position, which could adversely affect our financial reporting and operations.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be engaged by other companies or organizations and may have commitments that limit their availability, commercially reasonable terms, if at all. If we are unable to continue license software components on terms that permit our use for commercial purposes, we may be required to attract replace those software components, which could result in delays, additional cost and retain highly qualified personnel, additional regulatory approvals, and other adverse effects.

Use and distribution of open source software may entail greater risks than use of third-party commercial software, as open source licensors generally do not provide warranties or other contractual protections regarding infringement claims or the quality of the software code. Some open source licenses contain requirements that we make available source code for modifications or derivative works we create based upon the type of open source software we use. If we combine our proprietary software with open source software in a certain manner, we could, under certain of the open source licenses, be required to release the source code of our proprietary software to the public. This could allow our competitors to create similar products with lower development effort and time, and ultimately could result in a loss of product sales for us. Although we monitor our use of open source software, the terms of many open source licenses have not been interpreted by U.S. courts, and there is a risk that those licenses could be construed in a manner that could impose unanticipated conditions or restrictions on our ability to develop and commercialize our product candidates could be required to seek licenses from third parties in order to continue offering our product candidates, will be limited.

Our recent reduction in force undertaken to better align re-engineer our workforce with product candidates or to discontinue the needs sale of our business product candidates in the event re-engineering cannot be accomplished on a timely basis, any of which could materially and focus more of our capital resources on our pre-clinical program for remyelination in MS.

In February 2023, we implemented a reduction in force affecting approximately 55% of our workforce to better align our workforce with the needs of our business and focus more of our capital resources on our pre-clinical program for remyelination in MS. We believe these changes will preserve capital, ensuring that we are appropriately resourced to complete a first clinical trial of our MS Program. In connection with these actions, we will incur termination costs, which include severance costs and related expenses, which are estimated to be approximately \$4.0 million in future cash outlays.

The reduction in force may result in unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond the intended number of employees, decreased morale among our remaining employees, and the risk that we may not achieve the anticipated benefits of the reduction in force. In addition, while positions have been eliminated certain functions necessary to our operations remain, and we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees. The reduction in workforce could also make it difficult for us to pursue, or prevent us from pursuing, new opportunities and initiatives due to insufficient personnel, or require us to incur additional and unanticipated costs to hire new personnel to pursue such opportunities and initiatives. If we are unable to realize the anticipated benefits from the reduction in force, or if we experience significant adverse consequences from the reduction in force, adversely affect our business, financial condition, and results of operations may be materially adversely affected, and prospects.

We may engage in transactions that could disrupt if our business, cause dilution to our shareholders or reduce our financial resources.

In the future, we may enter into transactions to acquire or in-license rights to product candidates, products or technologies, or to acquire other businesses. If we identify suitable candidates, trademarks and trade names are not adequately protected, then we may not be able to enter into such transactions build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on unfavorable terms, or at all. Any such acquisitions or in-licenses other marks. We may not strengthen be able to protect our competitive position, rights to these trademarks and these transactions may be viewed negatively by analysts, investors, trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties with whom we have relationships. We may decide adopt trade names or trademarks similar to incur debt.

connection with an acquisition, ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trademark infringement claims

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brought by owners of other registered trademarks or issue our common stock or other equity securities as consideration for the acquisition, which would reduce the percentage ownership of trademarks that incorporate variations of our existing stockholders. We could incur losses resulting from undiscovered liabilities of registered or unregistered trademarks or trade names. Over the acquired business that long term, if we are not covered by the indemnification we may obtain from the sellers of the acquired business. In addition, unable to establish name recognition based on our trademarks and trade names, then we may not be able to successfully integrate the acquired personnel, technologies, compete effectively and operations into our existing business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in an effective, timely, substantial costs and nondisruptive manner. Such transactions may also divert management attention from day-to-day responsibilities, increase diversion of resources and could adversely affect our expenses, and reduce our cash available for business, financial condition, results of operations and other uses. We cannot predict the number, timing or size of future acquisitions or in-licenses or the effect that any such transactions might have on our operating results.

growth prospects.

Our business could be materially and operations would suffer adversely affected in the event future by the effects of security breaches or information technology system failures, disease outbreaks, epidemics and pandemics.

In the ordinary course of Disease outbreaks, epidemics and pandemics in regions where we may have clinical trial sites or other business operations could adversely affect our business, including by causing significant disruptions in our operations and/or in the operations of CROs upon whom we may rely. Disease outbreaks, epidemics and third parties with which we have relationships will continue negative impacts on our ability to collect and store sensitive data, including initiate new clinical data, proprietary business information, personal data sites, to enroll new patients and personally identifiable information to maintain existing patients who are participating in our clinical trials, which may include increased clinical trial costs, longer timelines and delay in our ability to obtain regulatory approvals of product candidates, if at all.

General supply chain issues may be exacerbated during disease outbreaks, epidemics and pandemics and may also impact the ability of our clinical trial subjects and employees, sites to obtain basic medical supplies used in data centers and on networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite the implementation of security measures, our computer systems, as well as those used in a timely fashion, if at all. If any of our CRO materials or components suppliers become subject to acts or orders of U.S. or foreign government entities to allocate or prioritize raw materials or components to the manufacture or distribution of vaccines or medical supplies needed to test or treat patients in a disease outbreak, epidemic or pandemic, this could delay our clinical trial perhaps substantially, which could materially and other contractors and consultants, adversely affect our business.

General Risk Factors

Our operations are vulnerable to attack, damage and interruption from computer viruses and malware (e.g. ransomware), malicious code, unauthorized access, malfeasance, natural and manmade disasters, (including hurricanes), terrorism, war, and telecommunication, electrical failures, hacking, cyberattacks, phishing attacks, terrorist activity, pandemics and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside events beyond our organization or persons with access to systems inside control, which could harm our organization.

Attacks upon information technology systems Our facilities are increasing located in their frequency, levels of persistence, sophistication and intensity, and are conducted by sophisticated and organized groups and individuals with expertise. We have not undertaken a wide range of motives and expertise. For instance, companies have experienced an increase in phishing and social engineering attacks from third parties in connection with COVID-19 global pandemic, and the recent hostilities between Russia and Ukraine may result in

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increased attacks that could either directly or indirectly impact us. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to potential consequences to our reliance on internet technology business and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized as attacks until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While such events, in addition, we do not believe sufficient insurance to compensate us for actual losses from interruption of our business that our network has experienced any significant system failure, accident, or security breach to date, if such an event were to occur, and cause interruptions in any losses or damages incurred by us could harm our business. The occurrence of any of these business disruptions could seriously harm our operations. It could result in delays and/or material disruptions of our research and development programs. For example, the loss of preclinical or clinical trial data from completed, ongoing, or planned trials could result in delays in our regulatory approval efforts. Financial conditions could significantly increase our costs to recover or reproduce and expenses.

Litigation costs and the data. Likewise, we currently rely and intend to rely in the future on third parties for the manufacture outcome of our product candidates and to conduct clinical trials, and similar events relating to their computer systems litigation could also have a material adverse effect on our business. If a security breach or other incident were to result in the unauthorized access to or unauthorized use, disclosure, release or other processing of personal information, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media and other parties pursuant to privacy and security laws. Any such access, disclosure, notifications, follow-up actions related to such a security breach or other loss of information could result in legal claims or proceedings, liability under data protection laws, and significant costs, including regulatory penalties, fines, and legal expenses, and such an event could disrupt our operations, cause us to incur remediation costs, damage our reputation, and cause a loss of confidence in us and our or such third party ability to conduct clinical trials, which could adversely affect our reputation and delay the clinical development of our product candidates.

Our employees work remotely and in a shared office with our sublessor, and from time to time we may be subject to heightened operational confidentiality litigation claims through the ordinary course of our business operations regarding, but not limited to, employment matters, security of employee personal information, contractual relations with third parties and cybersecurity risks. Intellectual property rights. Litigation to defend ourselves against claims of third parties, or to enforce any rights that we may have against third parties, may continue to be necessary, which could result in substantial costs, diversion of our resources, causing a material adverse effect on our business, financial condition, results of operations or cash flows.

Many Risks Related to Our Operations Following the Merger

If any of our employees work remotely from home at times. In addition, when the events described in "Risks Related to Our Business" occur, those events could cause potential benefits of the Merger not to be realized. To the extent any of the events in the office, our employees share an open, undivided office space with our sublessor. This subjects us to heightened operational risks. For example, technologies risks described in our employees' homes that section occurs, the potential benefits of the Merger may not be as robustly realized and our results of operations and financial condition could be adversely affected in a material way. This could cause the network information systems, applications, and other tools available to employees to be more limited or less reliable, and we may be subject to increased cybersecurity risk which could expose us to risks of data or financial loss. In our office, there are risks that individuals accessing our shared office space who are not associated with us may have access to confidential data, including from our clinical trials. There is no guarantee that the security and privacy safeguards we will put in place both for remote work and in our shared office space will be completely effective or that we will not encounter risks associated with unauthorized access to our data and information. If any of these were to occur, our business and operations could be materially adversely affected.

Risks related to our common stock

The market price of our common stock has been to decline.

The price of our common stock is volatile and fluctuates and may in future fluctuate substantially, which could result in substantial losses for our stockholders.

The price of our common stock has been, and is likely to continue to be, volatile. Some of the factors that may cause the market price of our common stock to be high, volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this section titled "Factors" and elsewhere in this Annual Report on Form 10-K, these factors include:

- any delay in the enrollment or ultimate completion of the planned Phase 1 study in our MS Program;
- the results of the planned Phase 1 study in our MS Program, or any future clinical trials and preclinical studies of our MS Program product candidates, trials of those of our competitors for the same or similar indication. For example, the price of our common stock decreased significantly following the announcement of our FX-322 Phase 2a (FX-322-202) interim results and our FX-322 Phase 2b (FX-322-208) results;
- our ability to develop our remyelination program in MS, existing or any additional product candidates based on our PCA approach;
- any delay in submitting a regulatory filing and any adverse development or perceived adverse development with respect to the regulatory review of our product candidates;
- failure to successfully develop an MS therapeutic or any future product candidates;

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- inability to obtain additional funding;
- regulatory or legal developments in the United States and other countries applicable to our PCA approach or any product candidate;
- adverse regulatory decisions;
- changes in the structure of healthcare payment systems;
- adverse developments concerning our CMOs or CROs;

- inability to obtain adequate product supply for our other product candidates, or the inability to do so at acceptable prices;
- introduction of new products, services or technologies by our competitors;
- our ability to effectively manage our growth; collaborators;
- failure to meet or exceed financial and development projections we may provide to the public;

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- failure to meet or exceed the estimates financial and development projections of the investment community;
- changes in if we do not achieve the market valuations perceived benefits of companies similar the Merger as rapidly or to us;
- market conditions in the biotechnology and pharmaceutical sectors, and the issuance of new extent anticipated by financial or changed securities analyst recommendations; industry analysts;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- the termination of a collaboration agreement, licensing agreement actions taken by regulatory agencies with respect to our product candidates, clinical manufacturing process or other strategic arrangement, or the inability to establish additional collaboration arrangements that we need on favorable terms; sales and marketing terms;
- significant lawsuits and their outcomes, including patent or shareholder litigation, and disputes or other developments relating to our proprietary rights, patents, litigation matters, and our ability to obtain patent protection for our product candidates and PCA approach; technologies;
- additions or departures of key scientific personnel;
- significant lawsuits, including patent or management personnel; stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading opinions regarding our business;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions or market conditions in the pharmaceutical and biotechnology sectors;
- sales of our common stock securities by us or our shareholders securityholders in the future;
- if we fail to raise an adequate amount of capital to fund our operations or continued development of our product candidates;
- trading volume of our common stock;
- announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to precision medicine product candidates, including with respect to other products in such markets;
- the introduction of technological innovations or new therapies that compete with our products and services; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general economic, industry have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In addition, a recession, depression or other sustained adverse market event could materially and market conditions, including adversely affect our business and the effects value of recession or slow economic growth our common stock. In the past, following periods of volatility in the U.S. market price of a company's securities, stockholders have often instituted class action securities litigation against such companies. Furthermore, market volatility may lead to increased shareholder activism if we experience a market valuation that activists believe is not reflective of our intrinsic value. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results, financial condition and abroad, interest rates, inflation rates, labor shortages, supply chain cash flows.

We may be unable to successfully integrate Frequency's and our businesses and realize the anticipated benefits of the Merger.

The Merger involved the combination of two companies that operated as independent companies. We are required to devote significant management attention and resources to integrating our business practices and operations. We may fail to realize some or all of the anticipated benefits of the Merger if the integration process takes longer than expected or is more costly than expected. Potential difficulties fuel prices, international currency fluctuations, corruption, political instability, acts we may encounter in the integration process include the following:

- the inability to successfully combine our businesses in a manner that permits us to achieve the anticipated benefits from the Merger, which would result in the anticipated benefits of war, including the hostilities between Russia Merger not being realized partly or wholly in the time frame currently anticipated or
- creation of uniform standards, controls, procedures, policies and Ukraine information systems; and

- potential unknown liabilities and unforeseen increased expenses, delays or regulatory conditions associated with the escalation of tensions between China and Taiwan, acts of terrorism, and the ongoing COVID-19 pandemic or other public health crises. Merger.

In addition, prior to the trading prices for common stock Merger, we operated independently. It is possible that the integration process also could result in the diversion of biopharmaceutical companies continue our management's attention, the disruption or interruption of, or the loss of momentum in our ongoing businesses, inconsistencies in standards, controls, procedures and policies, any of which could adversely affect our ability to be highly volatile maintain our business relationships, ability to achieve the anticipated benefits of the Merger, or could otherwise adversely affect our business and financial results.

We will incur additional costs and increased demands upon management as a result of complying with the COVID-19 pandemic laws and general market conditions, among other reasons. The COVID-19 pandemic and fluctuations in the global economy continue to evolve and remain unpredictable. The extent to which a regulations affecting public health emergency, such as the COVID-19 pandemic, may impact our business and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

Our directors, executive officers and shareholders affiliated with our directors and executive officers own a significant percentage of our common stock and they choose to act together, will be able to exert significant influence over matters subject to shareholder approval.

Our directors, executive officers, and shareholders affiliated with our directors and executive officers exert significant influence on us. As of December 31, 2022, these holders beneficially owned approximately 16.4% of the voting power of our outstanding common stock. As a result, these holders, acting together, have significant influence over all matters that require approval of our stockholders, including the election of directors, amendments of our organizational documents, or approval of an merger, sale of assets, or other major corporate transactions. The interests of these holders may not always coincide with our corporate interests or the interests of other shareholders, and they may act in a manner with which our shareholders may not agree or that may not be in the best interests of our other shareholders.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be the sole source of gain for our stockholders.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, our loan and security agreement with Silicon Valley Bank currently prohibits us from paying dividends on our equity securities, and any future debt agreements may likewise preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain on an investment in our common stock for the foreseeable future.

We will continue to incur increased costs as a result of operating as a public company, and our management will continue to devote substantial time to compliance initiatives and corporate governance practices.

As a public company, and particularly after we no longer qualify as an emerging growth company, we will continue to incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act requires operating Legacy Korro's business as a public company that it did not incur as a private company, including costs associated with public company reporting obligations under the Securities Exchange Act of 1934, as amended, or SOX, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Stock Market LLC, and other applicable securities rules and regulations impose various requirements on U.S. reporting companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management, executive officers and other personnel will need to devote a substantial amount of time to gaining expertise related to public company reporting requirements and compliance with applicable laws and regulations to ensure that we continue to comply with all of these compliance initiatives. Moreover, requirements. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, will continue to increase our legal and financial compliance costs and will make some activities more time consuming and costly. For example, these rules and regulations may make it more expensive for us to obtain director and officer liability insurance, which in turn potential litigation exposure associated with operating Legacy Korro's business as a public company, could also make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors. In addition, these rules may require directors or on board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

Once we are no longer an emerging growth company, a smaller reporting company or otherwise no longer qualify for applicable exemptions, we will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results and cash flows.

We are often subject to varying interpretations, the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition as a result, their application in practice may evolve over time well as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing review to other disclosure and corporate governance practices.

Pursuant requirements. However, as an emerging growth company, we may take advantage of exemptions from various requirements such as an exemption from the requirement to Section 404 of SOX, or Section 404, we are required have our independent auditors attest to furnish a report by our senior management on our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act of 2002 as well as an exemption from the "say on pay" voting requirements pursuant to the Dodd-Frank Wall Street Reform and our independent registered public accounting firm is required to provide an attestation report on our internal control over financial reporting. However, while we remain Consumer Protection Act of 2010. We will no longer qualify as an emerging growth company our independent registered public accounting firm will not be required to provide the attestation report. To ensure compliance with Section 404, after December 31, 2023. After we continue to engage in process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes no longer qualify as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, this could result in an adverse reaction on the price of our common stock in the market due to a loss of confidence in the reliability of our financial statements. Furthermore, if we are unable to conclude that our internal control over financial reporting is effective, our investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could decline.

We are an "emerging growth company" and a "smaller reporting company" and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and a "smaller reporting company" as defined under the rules promulgated under the Securities Act. As an emerging growth company and a smaller reporting company we may follow reduced disclosure requirements and do not have to make all the disclosures that public companies that are not emerging growth companies or smaller reporting companies do. We will remain an emerging growth company until the earlier of (a) the day of the fiscal year in which we have total annual gross revenues of \$1.07 billion or more; (b) the last day of the fiscal year following the fifth anniversary of the date of completion of our initial public offering; (c) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three years; or (d) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, or SEC, which means the market value of our voting non-voting common stock that is held by non-affiliates exceeds \$700 million as of the last business day of our second fiscal quarter. For so long as we remain an emerging growth company, we are permitted and intend expect to rely on still qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Exchange Act, in at least the near term, which will allow us to take advantage of many of the same exemptions from certain disclosure requirements, that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- including not being required to comply with the auditor attestation requirements of Section 404;
- an exemption from compliance with the requirement 404 of the Public Company Accounting Oversight Board Sarbanes-Oxley Act and reduced disclosure requirements regarding the communication of critical audit matters in the auditor's report on the financial statements;

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- progressively adding to the number of years of audited financial statements required to be included executive compensation in our periodic reports; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation, stockholder approval of any golden parachute payments previously approved and having to disclose the ratio of the compensation of our chief executive officer to the median compensation of our employees.

In addition, the JOBS Act provides that proxy statements. Once we are no longer an emerging growth company can take advantage of an extended transition period or a smaller reporting company or otherwise no longer qualify for complying these exemptions, we will be required to comply with new these additional legal and regulatory requirements applicable to public companies and will incur significant legal, accounting and other expenses to do so. If we are not able to comply with the requirements in a timely manner or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for complying with new or revised accounting standards; and as a result of this election, at all, our financial condition or the market price of our common stock may be harmed. For example, if we or our auditor identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses we could face additional costs to remedy those deficiencies, the market price of our stock could decline or we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements may not on a timely basis could be comparable to companies that comply with public company effective dates. impaired.

We are also a smaller subject to the reporting company, requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we will remain a smaller maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting company until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is more than \$250 million measured to allow management to report on the last business day of the fiscal year.

day effectiveness of our second fiscal quarter, or internal controls over financial reporting in our annual revenues are more than \$100 million during report on Form 10-I for that year, as required by Section 404 of the most recently completed fiscal year Sarbanes-Oxley Act. This will require that we incur substantial professional fees and internal costs to expand our voting accounting and non-voting common stock held by non-affiliates is more than \$700 million measured on the last business day financial functions and that we expend significant management efforts. We may experience difficulty in meeting these reporting requirements in a timely manner.

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We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our second fiscal quarter. Similar financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to emerging growth companies, smaller reporting companies error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to provide simplified executive compensation disclosure, are exempt from comply with the auditor attestation requirements of Section 404 and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, supplemental financial information or risk factors.

We may choose to take advantage of some, but not all, of the available exemptions for emerging growth companies Sarbanes-Oxley Act, or if we are unable to maintain proper and smaller reporting companies. We cannot predict whether investors will find effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our common stock less attractive if could decline and we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our shares price may be more volatile.subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

Our certificate of incorporation and bylaws and provisions under Delaware law could make an acquisition of us more difficult and may prevent attempts by stockholders to replace or remove our management.

Provisions in our restated certificate of incorporation, and our as amended, and restated bylaws or Delaware law may discourage, delay or prevent a merger, acquisition or other change in control of our company that our shareholders stockholders may consider favorable, including transactions in which our shareholders could stockholders might otherwise receive a premium price for their shares.

Our restated certificate of incorporation and our amended and restated bylaws include certain anti-takeover provisions, including those establishing:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death of a director, which prevents shareholders from filling vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferred voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws provisions of our restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be discussed at shareholders' meeting, which may discourage or deter a

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potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is will be responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that all members of the board are not elected at one time;

- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on at stockholder meetings;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call a special meeting of stockholders;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to the detriment of stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 66.67% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

In addition, Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of Delaware, the State of Delaware, DGCL, which prohibits a person who owns stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively will provide for a period an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of three years after directors, they would apply even if the date offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the person acquired in excess members of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, certain designated courts will be the exclusive forum for certain litigation that may be initiated by legal actions between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

Our restated certificate of incorporation specifies that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (1) state law claims for (i) any derivative action or proceeding brought on our behalf, (2) (ii) any action asserting a claim for or based on a breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders, (3) (iii) any action asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware, Delaware, or our restated certificate of incorporation, charter or our amended and restated bylaws, (4) any action to interpret, apply, enforce, or determine the validity of our restated certificate of incorporation or our amended and restated bylaws, or (5) (iv) any action asserting a claim that is governed by the internal affairs doctrine. Under our restated certificate doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants there which for purposes of this exclusive forum provision risk factor refers to herein as the "Delaware Forum Provision." The Delaware Forum Provision will not apply to claims which are vested in any causes of action arising under the exclusive jurisdiction of a court or forum other than Securities Act and the Court of Chancery of the State of Delaware, or for which the Court of Chancery of the State of Delaware does not have subject matter jurisdiction. In addition, our amended and restated Exchange Act. Our bylaws specify further provide that, unless we consent

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in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, will be the exclusive forum for the resolution of resolving any complaint asserting a cause of action arising under the Securities Act, which for purposes of 1933, this risk factor refers to hereafter as amended. These exclusive the "Federal Forum Provision." In addition, our bylaws provide that any person or entity purchasing or otherwise acquiring any interest in stock of our capital stock is deemed to have notice of and consented to the foregoing Delaware Forum Provision and Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived its compliance with the U.S. federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on our stockholders in pursuing any such claims, particularly if our stockholders do not reside in or near the State of Delaware. Additionally, the forum provisions selection clauses in our bylaws may limit a stockholder's ability to bring a claim in a judicial forum that it finds they find favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. For example, stockholders who employees even though an action, if successful, might benefit stockholders.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

The current expectation is that we will retain our future earnings, if any, to fund the growth of our business. Chancery could face additional litigation costs in pursuing our business as opposed to paying dividends. As a result, capital appreciation, if any, such claim, particularly of our common stock will be your sole source of gain, if they do any, for

foreseeable future.

An active trading market for our common stock may not reside in continue to develop or near the State be sustained and our stockholders may not be able resell their shares of Delaware. The Court common stock for a profit, if at all.

We cannot assure you that an active trading market for our shares of Chancery common stock may also reach different judgments continue to develop or result than would other courts, including courts where a stockholder considering be sustained. If an action active market for our common stock does not continue to develop or not sustained, it may be located difficult for our stockholders to sell their shares at an attractive price or would otherwise choose at all.

Future sales of shares by existing stockholders could cause our stock price to bring decline.

If our existing securityholders sell, or indicate an intention to sell, substantial amounts of our common stock in the action, public market after applicable legal and contractual restrictions on resale lapse, the trading price of our common stock could decline. Certain shares of our common stock are subject to a 180-day resale lock pursuant to certain lock-up agreement entered into prior to the closing of the Merger, and will be available for resale in the public market beginning 180 days after the of the Merger as a result of the expiration of such judgments or results may be more favorable to us lock-up agreements. All other outstanding shares of common stock other than shares held by our affiliates and shares issued in exchange for shares of Legacy Korro's common stock issued in the Pre-Closing Financing are freely tradable without restriction, in the public market. In addition, shares of common stock that are subject to our stockholders' outstanding options or warrants are eligible for sale in public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act. The enforceability market price similar choice the shares of forum provisions our common stock could decline as a result of the sale of a substantial number of our shares of common stock in other companies' certificates the public market or the perception in the market that the holders of incorporation has been challenged in legal proceedings, and it is possible in connection with any applicable action brought against us, a court could find the choice large number of forum provisions contained in our amended and restated certificate of incorporation shares intend to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provisions contained in our amended and restated certificate of incorporation or amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition, or results of operations. sell their shares.

General Risk Factors

Raising additional capital may cause dilution Our executive officers, directors and principal stockholders have the ability to control or significantly influence matters submitted to our stockholders restrict for approval.

Our executive officers, directors and principal stockholders, in the aggregate, beneficially own approximately 77% of our operations outstanding shares of common stock. As a result, if these stockholders were to choose to act together, they would be able to control or require us to relinquish rights significantly influence all matters submitted to our technologies stockholders for approval, as well as our management and affairs. For example, these stockholders, if they choose to act together, would control or product candidates.

Until such time, if ever, as we can generate substantial revenues, we may finance our cash needs through a combination significantly influence the election of offerings, debt financings, marketing directors and distribution arrangements and other collaborations, strategic alliances and licensing arrangements approval of any re consolidation or other sources. We do not currently have any committed external source of funds. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the sale of equity all or convertible debt securities, our existing stockholders' ownership interests will be diluted and the terms of these securities may include liquidation or other preferences that adversely affect the rights substantially all of our common stockholders. In addition, financing and preferred equity financing, if available, may involve agreements that include covenants limiting assets. This concentration of voting power could delay or restricting our ability to take specific

actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, intellectual property, future re streams or product candidates or grant licenses prevent an acquisition of us on terms that other stockholders may not be favorable to us. Furthermore, any capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to advance research programs, product development activities product candidates. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate product candidate development or commercialization efforts.

We may be subject to claims by third parties asserting that our employees, consultants or contractors have wrongfully used or disclosed confidential information of third parties, or we have wrongfully used or disclosed alleged trade secrets of their current or former employers, or claims asserting we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, consultants and contractors were previously employed at universities or other pharmaceutical or biotechnology companies, including competitors or potential competitors. In addition, we share an undivided, open office space with our sublessor, and our employees or other individuals who are in our c may have access to information regarding our sublessor's business, including potentially proprietary information. Although we try to ensure that our employees, consu

and contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our intellectual property assignment agreements with them may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

If we fail in prosecuting equity research analysts do not publish research or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, reports, or personnel, which could have a material adverse effect on our competitive business position and prospects. Intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology, publish unfavorable research or products, which license may not be available on commercially reasonable terms, or at all, or such license may be non-exclusive. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management and employees.

We are currently subject to securities class action and other shareholder litigation and could be subject to similar or other litigation in the future.

In the past, securities class action and other shareholder litigation has often been brought against companies following a decline in the market price of their securities. This risk is especially relevant for reports about us, because biotechnology and pharmaceutical companies have experienced significant share price volatility in recent years. See Note 16, "Commitments and contingencies – Legal Contingencies", for a description of our material legal proceedings.

We can make no assurances as to the time or resources that will need to be devoted to these lawsuits or their final outcomes, or the impact, if any, of these lawsuits or any proceedings on our business financial condition, results of operations and cash flows. While we are vigorously defending against all claims asserted, these lawsuits could result in substantial costs to us and a diversion of our management's attention and resources, which could harm our business. In addition, the uncertainty of the pending lawsuits or potential filing of additional lawsuits could lead to more volatility and a reduction in our stock price.

If securities or industry analysts issue an adverse or misleading opinion regarding our common stock, market, our stock price and trading volume could decline.

The trading market for our common stock is will be influenced by the research and reports that industry or securities equity research analysts publish about us and our business. If equity research analysts may elect to not provide research coverage of our common stock following the Merger, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any of control over the analysts who cover us issue an adverse or misleading opinion regarding us, the content and opinions included in their reports. The price of our business model, our intellectual property common stock could decline if one or more equity research analysts downgrade our stock performance, or if our clinical studies and operating results fail to meet the expectations of analysts, our stock price would likely decline, issue other unfavorable commentary or research. If one or more of these equity research analysts cease coverage of us or fail to issue

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publish reports on us regularly, we demand for our common stock could lose visibility in the financial markets, decrease, which in turn could cause our stock price or trading volume to decline.

We will have broad discretion in the use of our cash and cash equivalents and the proceeds from the Pre-Closing Financing and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.

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The trading price We will have broad discretion over the use of our common stock has been highly volatile.

The trading price cash and cash equivalents, including the proceeds from the Pre-Closing Financing. You may not agree with our decisions, and our use of our common stock has been highly volatile, particularly over the last year. For example, proceeds may not yield any return on December 31, 2021, the closing price of our common stock was \$5.13 per share and on December 31, 2022 it was \$3.85 per share. your investment. Our stock price is likely failure to continue to be volatile and subject to significant price and volume fluctuations in response to market and economic factors that are beyond our control. In addition, while the stock market in general has experienced high volatility, biotechnology companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to operating performance. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

Sales of a substantial number of shares of our common stock, or the perception that substantial sales might occur, apply these resources effectively could cause the price of our common stock to fall.

Sales of a substantial number of shares of our common stock, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment in these net proceeds. You will not have the sale of additional equity securities. The shares of common stock that were sold in the initial public offering of opportunity to influence our common stock are freely transferable without restrictions or further registration under the Securities Act of 1933, as amended, or the Securities Act, except any shares acquired by decisions on how to use our affiliates, as defined in Rule 144 under the Securities Act. The remaining shares of our common stock that are outstanding are either unrestricted or restricted as a result of securities laws. In addition, there are shares of common stock that are either subject to outstanding options reserved for future issuance under our existing equity incentive plans and may become eligible for future sale subject to vesting, and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. cash resources.

The increasing focus on environmental sustainability and social initiatives could increase our costs, harm our reputation and Changes in tax laws or in implementation or interpretation may adversely impact our financial results.

There has been increasing public focus by investors, customers environmental activists, the media and governmental and nongovernmental organization variety of environmental, social and other sustainability matters. We may experience pressure to make commitments relating to sustainability matters that affect including the design and implementation of specific risk mitigation strategic initiatives relating to sustainability. If we are not effective in addressing environmental, social and other sustainability matters affecting our business, or setting and meeting relevant sustainability goals, our reputation and financial results may suffer. We may experience increased costs in order to execute upon our sustainability goals and measure achievement of those goals, which could have an adverse impact on our business financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our business and financial condition. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, under Section 174 of the Code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the U.S. are capitalized and amortized, which have an adverse effect on our cash flow. In addition, this emphasis on environmental, social it is unclear how these U.S. federal income tax changes will affect state and local taxation. We cannot predict whether, when, in what form or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or decided or whether they could increase our tax liability or require changes in the manner in which we operate in order to minimize increases in our tax liability.

Our ability to use NOL carryforwards and other sustainability matters has resulted tax attributes may be limited, including as a result of the Merger.

Our ability to utilize NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes including, as discussed below, in connection with the Merger or other transactions. Similar rules may apply under state tax laws. If we earn taxable income, such limitation could result in the adoption of new laws increased future income tax liability to us, and regulations, including new reporting requirements. If we fail to comply with new regulations or reporting requirements, our reputation and business future cash flows could be adversely impacted, affected.

For a more complete discussion of the risks related to the net operating loss carryforwards and certain of our other tax attributes, please see the discussion under "Risks Related to Our Financial Position and Need for Capital—Our ability to utilize our net operating loss, or NOL, carryforwards and certain other tax attributes may be limited."

Financial volatility Unfavorable global economic conditions could adversely affect our business, financial condition, results of operations or geopolitical instability outside of the U.S. may adversely impact the U.S. cash flows.

We Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Global credit A severe prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial markets have experienced volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, rising interest rates, declines in consumer confidence, declines in economic growth, increase in unemployment rates and uncertainty about economic stability. Our business stock price may be adversely affected by any such economic downturn, volatile business environment or large-scale unpredictable or unstable market conditions including the recent hostilities between Russia and Ukraine and the escalation of tensions between China and Taiwan which could have a lasting adversely impact on regional and global economies.our business.

Item 1B. Unresolved Staff Comments.

None.

None Item 1C. Cybersecurity

Cybersecurity Risk Management and Strategy

We recognize the importance of assessing, identifying, and managing risks from cybersecurity threats. We have implemented a cybersecurity risk management process in accordance with our risk profile and business that is informed by industry standards and is integrated into our enterprise risk management process.

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We leverage the support of third-party information technology and security providers, including for periodic security testing and risk assessments, as part of our management process, designed to identify, assess, and manage cybersecurity risks. We conduct employee cybersecurity training and maintain an incident response and notification plan designed to assist us in identifying, responding to, and recovering from cybersecurity incidents. Further, we intend to evaluate and update our existing cybersecurity policies and procedures as appropriate to continue to align them to our risk profile.

We have a process to assess the security practices of certain third-party vendors, including through the use of vendor security questionnaires, as appropriate.

Although risks from cybersecurity threats have to date not materially affected us, our business strategy, results of operations or financial condition, we have, from time to time, experienced threats to and breaches of our and our third party vendors' data and systems. For more information about these risks, see Item 1A "Risk Factors - Risks Related to Our Business."

Governance Related to Cybersecurity Risks

Our Vice President, Information Technology, or Vice President, who reports to the Chief Operating Officer, is responsible for the strategic leadership and direct management of our cybersecurity program. With over 20 years of experience in information technology, the Vice President works alongside individuals across other functions, such as legal and engineering, to establish and implement our cybersecurity strategy.

The Vice President and our Chief Operating Officer and General Counsel participate in periodic discussions with other members of our management, including executive leadership, regarding implementation of our cybersecurity program, program enhancements, and relevant cybersecurity risks or threats.

Our audit committee has oversight over cybersecurity risks. With the input of the executive team, the Vice President provides annual presentations to the audit committee on our cybersecurity program, including updates on cybersecurity testing and assessments, cybersecurity risks, and related cybersecurity strategy as applicable. The management team will also update the full board of directors on matters related to cybersecurity as needed.

Additionally, we have implemented an enterprise risk management process, which addresses cybersecurity risks. This process is led by our General Counsel and includes participation by the board of directors, as appropriate. Our General Counsel reports regularly on the enterprise risk management process to executive leadership and the audit committee.

Item 2. Properties.

Our principal office is located at 75 Hayden Avenue, Lexington, Massachusetts 02421, One Kendall Square, Building 600-700, Suite 6-401, Cambridge, MA 02142 where we lease approximately 61,307 square feet of office and laboratory space. The lease term commenced began in August 2020 and will end in September 2021. We also lease 18,148 square feet of laboratory and office space at 42 & 45 Cummings Park in Woburn, Massachusetts. We have plans to relocate our headquarters to occupy 50,453 square feet of laboratory and office space at 60 First Street in Cambridge, Massachusetts upon completion of the buildout of the space in 2024. We believe that these facilities will be adequate for our near-term needs. If required, we believe that suitable additional or substitute space will be available in the future on December 11, 2020 and expires on May 31, 2031.

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commercially reasonable terms to accommodate any such expansion of our operations.

Item 3. Legal Proceedings.

From time to time, we may be involved in various other claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any material legal proceedings other than as disclosed below.

On June 3, 2021 and June 22, 2021, purported stockholders of Frequency filed putative class action lawsuits in the U.S. District Court for the District of Massachusetts against the Frequency and the Frequency's Chief Executive Officer, President, and Director, David Lucchino. On March 21, 2022, the two lawsuits were consolidated into a single lawsuit, Quinones et al. v. Frequency Therapeutics, Inc. et al. and on May 16, 2022, Frequency's Chief Development Officer, Dr. Carl Le Bel was added as a defendant. The plaintiffs alleged violations of Sections 10(b), 20(a) and Rule 10b5 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, due to allegedly false and misleading statements and omissions about Frequency's Phase 2a clinical trial (FX-322-202) for its product candidate FX-322 in Frequency's public disclosures between October 29, 2020 and March 22, 2021. The lawsuit sought, among other things, damages in connection with Frequency's allegedly artificially inflated stock price between October 29, 2020 and March 22, 2021 as a result of those allegedly false and misleading statements and omissions, as well as interest, attorneys' fees and costs. On March 29, 2023, Frequency's motion to dismiss was granted and the lawsuit was dismissed in its entirety. On April 27, 2023, Plaintiff filed

notice of appeal to the United States Court of Appeals for the First Circuit from the order dismissing the lawsuit. On August 2, 2023, Plaintiff-Appellant submitted its opening brief to the

See Note 16, “96

Commitments

First Circuit. Frequency filed its response brief on October 27, 2023. The First Circuit heard oral argument on January 8, 2024, and contingencies – Legal Contingencies for more information. has not yet issued a decision on plaintiff’s appeal. The Company intends to vigorously defend against the lawsuit.

Item 4. Mine Safety Disclosures.

Not applicable.

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PART II

Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is traded listed on the Nasdaq Capital Market under the symbol “FREQ” on the Nasdaq Global Select Market. “KRRO”.

Holders of Our Common Stock

On February 1, 2023 As of March 1, 2024, there were approximately 67 registered holders we had 8,020,788 shares of common stock issued and outstanding of record of our common stock. by 96 holders. The actual number of stockholders holders of these securities is greater than this number of record holders, and as the number includes stockholders holders who are beneficial owners but whose shares securities are held in street name by brokers and other nominees. The This number holders of record also does not include stockholders holders whose shares securities may be held in trust by other entities.

Recent Sales of Unregistered Securities

Dividend Policy

We have never declared or paid any dividends on our capital stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends is made at the discretion of our board of directors and will require approval from Silicon Valley Bank under the terms of our loan and security agreement. Investors should purchase our common stock with the expectation of receiving cash dividends. None.

Equity Compensation Plan Information

Equity Information about our equity compensation plan information will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and plans is incorporated herein by reference. reference to Item 12 “Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters”

Recent Sales of Unregistered Equity Securities

During the period covered by this Annual Report on Form 10-K, we did not issue any securities which were unregistered under 10-K.

Purchases of Equity Securities by the Securities Act and required to be disclosed herein. Issuer or Affiliated Purchasers

None.

In October 2019, we issued and sold 6,325,000 shares of our common stock in our initial public offering, or IPO, at a public offering price of \$14.00 per share. offer and sale of all the shares in the IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-233652), as amended, which was declared effective by the SEC on October 2, 2019.

The \$79.7 million in net proceeds we received from the IPO have been invested in cash and cash equivalents. There has been no material change in the expected use of the net proceeds from our IPO as described in our final prospectus, dated October 2, 2019, filed with the SEC pursuant to Rule 424(b) relating to our registration statement on Form S-1 on October 4, 2019.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our audited consolidated financial statements and the related notes and other financial information included elsewhere in this Annual Report on Form 10-K. In addition to historical information contained in this discussion and analysis, contains including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as uncertainties. As a result of certain factors. We discuss many factors, that we believe could cause or contribute to these differences below and elsewhere in this report including those factors set forth under Item 1A, the heading "Risk Factors" and under "Forward-Looking Statements" in this Annual Report. You should review the section titled "Risk factors" in Part I, Item 1A of this Annual Report on Form 10-K for a discussion of important factors that could cause our actual results to differ materially from the results described below.

in or implied by the forward-looking statements contained in the following discussion and analysis. See also "Cautionary Statement Regarding Forward-Looking Statements."

Overview

We are pioneering a biopharmaceutical company with a mission to discover, develop and commercialize a new category in regenerative medicine that aims to restore human function by developing therapeutics that activate a person's innate regenerative potential within a class of genetic medicines based on editing RNA, enable the body through the activation/treatment of progenitor cells. We believe our progenitor cell activation, or PCA, approach can impact a wide range of degenerative and highly prevalent diseases. Our lead preclinical program is designed to activate oligodendrocyte precursor cells with the goal of inducing remyelination and potential functional recovery for individuals living with multiple sclerosis (MS).

Our first application of this technology was for the restoration of the cochlea, with a focus on treating sensorineural hearing loss, or SNHL, which is the most prevalent type of hearing loss. Our lead cochlear regeneration program, FX-322, was designed to treat the underlying cause of SNHL by regenerating cells in the inner ear required for hearing through the activation of progenitor cells already present in the cochlea. Since 2019, we ran five FX-322 clinical studies, all with the aim of understanding safety as well as severities and etiologies that FX-322 might treat and the appropriate dose regime. In several of these studies, we observed that a single dose of FX-322 was associated with statistically significant improvements in hearing function as measured by improved speech perception in subjects with SNHL giving us confidence in the potential of FX-322 as a potential drug candidate for hearing loss.

In 2021 we commenced our sixth study, a Phase 2b clinical trial of FX-322 (FX-322-208), a randomized, placebo-controlled, multi-center study designed to evaluate the impact of a single administration of FX-322 on speech perception in 124 subjects, ultimately enrolling 142 subjects, with either noise-induced or sudden SNHL, the hearing loss severities and etiologies as those subjects in which statistically significant improvements in speech perception were observed in prior FX-322 clinical trials. The study's primary endpoint was speech perception, a measure of sound clarity and understanding speech. In a Type-C meeting, the FDA agreed that speech perception was an acceptable primary efficacy endpoint. In February 2023, we announced results of FX-322-208 and that the study failed to achieve its primary endpoint of an improvement in speech perception. Data showed no statistically significant difference at day 90 between those administered FX-322 versus those receiving placebo in the proportion of individuals that demonstrated an improvement in speech perception. There were also no measurable improvements observed in any of the study's secondary endpoints. As a result of this outcome, we decided to discontinue the FX-322 development program.

Also in 2021, we introduced a second hearing program, called FX-345, which we believed might expand the opportunity to treat different types of SNHL as FX-322 was designed to achieve exposure at desired drug concentrations through a large portion of the cochlea. Cochlear pharmacokinetic measures and human modeling data from a preclinical setting showed that FX-345 achieved exposure at desired concentrations through a larger portion of the cochlea for longer time as compared to FX-322. The FX-345 program commenced dosing in a Phase 1b study (FX-345-101) in December 2022, completing an initial safety cohort. Given the outcome of the FX-322 study and the similarities of the two candidates in design, intended mechanism of action, and clinical design components we decided to discontinue the FX-345 development program.

program as well. Ceasing development of our hearing program, while a difficult decision, will allow us to focus our resources to advance the remyelination in MS program into the clinic.

We are now working generating a portfolio of differentiated programs that are designed to rapidly advance discovery efforts harness the body's natural RNA editing process to effect a precise yet transient single base edit. By editing RNA instead of DNA, we are expanding the reach of genetic medicines by delivering additional precision and tunability, which has the potential for increased specificity and improved long-term tolerability. Using an oligonucleotide-based approach, we expect to bring our medicines to patients by leveraging our proprietary platform with precedented delivery modalities, manufacturing know-how, and established regulatory pathways of approved oligonucleotide drugs. However, the scientific evidence to support the feasibility of developing product candidates using our PCA approach RNA editing technology is both preliminary and limited. Moreover, regulators have not yet established any definitive guidelines related to potentially remyelinate neurons in individuals with MS induces demyelination, stripping axons of the myelin sheaths that support neuronal signal conduction overall development considerations for RNA editing therapies an axonal survival. We previously reported that we had identified a novel target relevant no clinical data has been generated to myelination. Modulation of this target induces robust oligodendrocyte differentiation and expression of myelin proteins *in vitro*. We have identified multiple novel chemical entities that induce robust remyelination following demyelination in an adult *in vivo* animal model.

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date.

The MS Program is independent versatility of RNA editing combined with our OPERA platform broadens the hearing therapeutic target space significantly. This approach can be used to repair pathogenic single nucleotide variants, or SNVs, as demonstrated by our most advanced program, our Alpha-1 Antitrypsin Deficiency, or AATD, product candidate, we can also engineer de novo SNVs and change amino acids on proteins to endow them with desired properties while preserving their broad functional capabilities, as exemplified by three of our other programs (severe Alcoholic Hepatitis, or SAH, amyotrophic lateral sclerosis, or ALS, Pain). In preclinical studies we have demonstrated that single RNA changes can disrupt protein-protein interactions, prevent protein aggregation, selectively modulate ion channels and activate kinases. These modification approaches can unlock validated target classes that have historically been difficult to drug, enabling us to pursue a distinct molecular target mechanism, progenitor cell population, broad range of diseases traditionally out-of-scope for other genetic medicine approaches and small molecule current traditional candidates. Further, a well-defined clinical path with objective biomarkers such as visual evoked potential (VEP) and magnetic resonance imaging (MRI) exist for studying the performance of remyelination therapies in MS patients. Our novel agents substantially outperform other clinically studied remyelination agents in head-to-head *in vivo* studies. We plan to begin our clinical program for remyelination in MS in the first half of 2024, modalities.

On April 8, 2022, Our most advanced program is a development candidate, KRRO-110, for the treatment of AATD where, using our proprietary RNA editing approach, we announced are repairing a reduction pathogenic variant on RNA. KRRO-110 has the potential to be disease-modifying and provide a differentiated therapeutic option. Preclinical development of KRRO-110 is ongoing in force of approximately 30% of our workforce to better align our workforce with the near-term needs of our business and focus more of our capital resources on our research and development programs preparation for hearing and remyelination in MS. On February 13, 2023 announced a restructuring of our business including the discontinuation our hearing program and a downsizing of personnel by approximately 55%. We believe these changes will generate sufficient cost savings to enable us to complete a first clinical trial of our MS Program potential regulatory filing in the second half of 2024 with a runway into and an anticipated interim clinical readout in the second half of 2025.

Since our formation in 2014, inception, we have devoted substantially all focused primarily on organizing and staffing our resources to developing our PCA approach, company, business planning, raising capital, securing related intellectual property, and conducting research and development activities including for our potential programs and product candidate development, recruiting skilled personnel, establishing our intellectual property portfolio, and providing general and administrative support for these operations. We candidates. Since inception, we have financed funded our operations primarily through the private placement of our equity securities. To date have raised approximately \$223.6 million of aggregate gross proceeds from the sale of our convertible preferred stock, and public securities financings, \$117.3 million the sale of shares of common stock issued in a term loan, and amounts received under a collaboration agreement. private placement that closed immediately prior to the Merger (as defined below), or the Pre-Closing Financing.

Since our formation, we We have incurred significant operating losses since inception. Our net losses were \$81.2 million and \$58.0 million for the years ended December 31, 2023 and 2022, respectively. We had an accumulated deficit of \$183.0 million as of December 31, 2023. We expect to continue to incur significant and increasing expenses and operating losses and negative operating cash flows for the foreseeable future as we continue our research and development efforts, advance product candidates through clinical stages, and seeks regulatory approvals for its pipeline candidates. As a result of the Merger (as defined below), we also expect to additional costs associated with maintaining compliance with Nasdaq listing rules and the requirements of the U.S. Securities and Exchange Commission, or SEC, director and officer liability insurance, investor and public relations activities and other expenses associated with operating as a public company. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of its preclinical studies, initiation and conduct of any clinical trials, and its expenditures other research and development activities, including the expansion of its pipeline.

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We do not have any product candidates approved for sale and have not generated any revenue from the sale of products. Our ability to generate any product revenue or product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more of our product candidates. Our net losses were \$81.6 million and \$84.7 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of \$261.7 million. During the periods presented, we do not have any off-balance sheet arrangements.

Our operating expenses discussed in this section reflect our development programs around FX-322, FX-345, MS and any future programs as well as our operations as a public company. sales. We will not generate revenue from product sales unless and until we successfully complete clinical development, obtain regulatory approval and successfully commercialize our product candidates, or until if ever, and as appropriate, move pipeline candidates into the clinic and complete clinical development have yet to commence clinical trials on any of our collaborators do so, which could result in milestone payments or royalties to us. program candidates. If we obtain regulatory approval for any of our product candidates and do not enter into third-party commercialization partnerships, we expect to incur significant expenses related to developing our commercialization capability capabilities to support product sales, marketing, manufacturing and distribution.

distribution activities. As a result, of these anticipated expenditures, we will need substantial additional financing funding to support our continuing operations. operations and pursue our development and growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our cash needs operations through a combination of public or private equity or offerings of securities, debt financings and or other sources, which such as potential collaboration agreements, strategic alliances and licensing arrangements. We may include current and new collaborations with third parties. Adequate be unable to raise additional financing may not be available to us funds or enter into such other agreements or arrangements when needed on acceptable terms, or at all. Our inability fail to raise capital or enter into such agreements as, and when needed, would could have a negative impact effect on its business, results of operations and financial condition.

Recent Developments

Merger Agreement & Pre-Closing Financing

On July 14, 2023, we entered into the Merger Agreement with the private company formerly known as Korro Bio, Inc., or Legacy Korro, and Frequency Merge Inc., our wholly-owned subsidiary, or Merger Sub. Pursuant to the Merger Agreement, on November 3, 2023, or the Closing Date, following approval by our stockholders and Legacy Korro's stockholders, Merger Sub merged with and into Legacy Korro, or the Merger, with Legacy Korro continuing as our wholly owned subsidiary and the surviving corporation of the Merger. The Merger is intended to qualify as a "reorganization" within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended. The Merger Agreement was approved by the members of the board of directors of both our company and Legacy Korro. In connection with the completion of the Merger, we changed our name from Frequency Therapeutics, Inc. to Korro Bio, Inc. The merger was accounted for as a reverse recapitalization and accordingly, the financial statements of Legacy Korro became our financial statements. Except as otherwise indicated, references herein to "we", "us" or the "Company", refer to Korro Bio, Inc. on a post-merger basis; references to "Legacy Korro" refer to the business of privately held Korro Bio, Inc., prior to completion of the merger; and references to Frequency refer to Frequency Therapeutics, Inc. prior to completion of the merger.

Immediately prior to the execution of the Merger Agreement, certain new and existing investors of Legacy Korro agreed to purchase shares of Legacy Korro's common stock at \$2.78 per share for the aggregate amount of \$117.3 million in the Pre-Closing Financing. The Pre-Closing Financing was contingent on and closed immediately prior to consummation of the Merger.

Subject to the terms and conditions of the Merger Agreement, immediately prior to the Closing Date, each then outstanding share of Legacy Korro's common stock (including common stock issued upon the conversion of Legacy Korro's preferred stock but excluding the common stock issued in the Pre-Closing Financing) converted into the right to receive 5,161,114 shares of our common stock calculated in accordance with the Merger Agreement (which takes into account the 1-for-50 reverse stock split of our common stock effected immediately prior to the Merger).

Shares of Legacy Korro's common stock issued pursuant to the Pre-Closing Financing were converted into the right to receive 2,077,864 shares of our common stock calculated in accordance with Merger Agreement at the effective time of the Merger (which takes into account the 1-for-50 reverse stock split of our common stock effected immediately prior to the Merger).

Financial Operations Overview

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery of novel genetic medicines and the development of our product candidates, salaries and benefits, and third-party license fees. We expense research and development costs as incurred, which include:

- employee-related expenses, including salaries, bonuses, benefits, stock-based compensation and other related costs for those employees involved in development efforts;
- external research and development expenses incurred under agreements with contract research organizations, or CROs as well as with consultants;
- laboratory supplies and research materials;

- payments made under third-party licensing agreements; and
- direct and allocated expenses for facilities.

Costs for certain activities are recognized based on an evaluation of the progress to completion of specific tasks using data such as information provided to us our vendors and analyzing the progress of our preclinical studies or other services performed. Significant judgment and estimates are made in determining the accrue expense balances at the end of any reporting period.

Our external research and development expenses consist primarily of fees paid to CROs and outside consultants in connection with our preclinical developme activities. Our external research and development expenses also include fees incurred under license agreements. As a pre-clinical company, we do not yet track these external research and development costs on a program-by-program basis. We plan to track program costs on our financial condition lead development candidate KRR upon filing of an Investigational New Drug, or IND, application.

We characterize research and development costs incurred prior to the identification of a product candidate as discovery costs. We use internal resources prim conduct our ability research and discovery activities as well as for managing our preclinical development activities.

The successful development of our product candidates is highly uncertain. We plan to pursue substantially increase our business strategy, research and development expenses for the foreseeable future as we continue the development of our product candidates, conducts discovery and research activities for our precli programs, and expands our pipeline. We cannot be sure determine with certainty the timing of initiation, the duration or the completion costs of current or future preclir studies and clinical trials of our product candidates due to the inherently unpredictable nature of preclinical and clinical development. Clinical and preclinical developm timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will ever generate sufficient revenue make determinations as to achieve profitability.

Because which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and preclinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. Our clinical develop costs are expected to increase significantly as we commence clinical trials. We anticipate that our expenses will increase substantially, particularly due to the numerou and uncertainties associated with the development of therapeutics, we are unable to predict the timing or amount of increased expenses or when or if we will be able t achieve or maintain profitability. Even if we can generate revenue from developing product sales, we may not become profitable. If we fail to become profitable or are t to sustain profitability on a continuing basis, then we may be required to raise additional capital on terms that are unfavorable to us or we may be unable to continue o operations at planned levels and be forced to reduce or terminate our operations.

License and collaboration agreements

Astellas Pharma Inc.

In July 2019, we entered into the Astellas Agreement with Astellas, under which we granted Astellas an exclusive, royalty-bearing, sub-licensable, nontransfer license to certain patent rights to research, develop, manufacture, have manufactured, use, seek, and secure regulatory approval for, commercialize, offer for sale, sel have sold and import, and otherwise exploit licensed products containing both a GSK-3 inhibitor and an HDAC inhibitor, or the Astellas licensed products, including ou product candidate FX-322, outside of the United States. We and Astellas have agreed to jointly develop the Astellas licensed products, including carrying out joint stur Each party has agreed to use commercially reasonable efforts to carry out development activities assigned to it under an agreed-upon development plan. Astellas has agreed to use commercially reasonable efforts to obtain regulatory approval for at least one Astellas licensed product in SNHL and in age-related hearing loss, in each in one major Asian country and one major European country. We have agreed to use commercially reasonable efforts to obtain regulatory approval for at least one As licensed product in the United States. Astellas has the sole right to commercialize the Astellas licensed products outside of the United States and we

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have the sole right to commercialize the Astellas licensed products in the United States. Astellas has agreed to use commercially reasonable efforts to commercialize Astellas licensed products in a major Asian country and a major European country following receipt of regulatory approval in such countries.

As consideration for the licensed rights under the Astellas Agreement, Astellas paid us an upfront payment of \$80.0 million in July 2019 and has agreed to pay potential development milestones up to \$230.0 million. Specifically, we would receive development milestone payments of \$65.0 million and \$25.0 million upon the first dosing of a subject in Phase 2b clinical trial for SNHL in Europe and Asia, respectively and \$100.0 million and \$40.0 million upon the first dosing of a subject in a Phas clinical for SNHL in Europe and Asia, respectively. If the Astellas Licensed Products are successfully commercialized, we would be eligible for up to \$315.0 million in potential commercial milestone payments and tiered royalties at rates ranging from low to mid-teen percentages. The parties shall share equally, on a 50/50 basis, all pocket costs and joint study costs for all the joint activities conducted pursuant to the development plans or the joint manufacturing plan. Pursuant to our Exclusive Pa License Agreement, or the MIT License, with the Massachusetts Institute of Technology, or MIT, we are required to pay MIT a royalty on sublicense revenues. A royalt \$16.0 million related to the \$80.0 million upfront payment received from Astellas was expensed in the quarter ended September 30, 2019 and paid in November 2019. \$80.0 million upfront payment received from Astellas in July 2019 was recorded as deferred revenue and recognized as revenue, using the input method, over the per from execution of the agreement through June 30, 2021, when the Phase 2a clinical trials were completed.

Massachusetts Institute of Technology

In December 2016, we entered into the MIT License, with MIT under which we received an exclusive, worldwide, royalty-bearing license to certain patent rights to develop, make, have made, use, sell, offer to sell, lease, and import products, or the MIT licensed products, and to develop and perform processes, or the MIT license processes, which incorporate the licensed technology for the treatment of disease, including but not limited to the prevention and remediation of hearing loss. We are required to use diligent efforts to develop and commercialize the MIT licensed products or processes, and to make such products or processes reasonably available to the public. We are also subject to certain development obligations with regards to a first MIT licensed product. We have satisfied certain obligations related to preclinical studies and the filing of an IND for a first MIT licensed product with our development activities related to FX-322. Our future development obligations are: (i) to commence a Phase 1 clinical trial for such product within five years of the IND filing for such product, (ii) to file a New Drug Application, or NDA, or equivalent with the FDA or comparable European regulatory agency for such product within nine years of the IND filing for such product, and (iii) to make a first commercial sale of such product within 11 years of the IND filing for such product. We also have certain development obligations with regards to a second MIT licensed product.

Upon entering into the MIT License, we paid a \$50 thousand license fee payment and issued shares of our common stock equal to 5% of our then-outstanding capital stock to MIT. We are required to pay certain annual license maintenance fees ranging from \$30 thousand to \$0.1 million per year prior to first commercial sale of a MIT licensed product and an annual license maintenance fee of \$0.2 million every year afterwards, which may be credited to running royalties during the same calendar year, if any. We are also required to make potential milestone payments in an aggregate amount of up to \$2.9 million on each MIT licensed product or process. In addition, we agreed to pay a low single-digit royalty on the MIT licensed products and processes and a low-twenties royalty on sub-license revenues.

In May 2019, we entered into an amendment with MIT, updating the diligence milestones for a second Licensed Product.

In March 2022, we entered into an amendment with MIT, removing a patent and certain patent applications from the MIT License Agreement which were unrelated to our hearing and MS programs and which we were not utilizing.

Massachusetts Eye and Ear (Formerly Massachusetts Eye and Ear Infirmary)

In February 2019, we entered into a Non-Exclusive Patent License Agreement, or the MEE License, with the Massachusetts Eye and Ear, or MEE, under which we received a non-exclusive, non-sub-licensable, worldwide, royalty-bearing license to certain patent rights to develop, make, have made, use, sell, offer to sell, lease, and import products, and to develop and perform processes that incorporate the licensed technology for the treatment or prevention of hearing loss, or the MEE licensed products. We are obligated to use diligent efforts to develop and commercialize the MEE licensed products. We met one of our milestone timeline obligations by dosing the first subject in a Phase 2 trial by December 31, 2020. We are still subject to a milestone timeline obligation to dose a first subject in a Phase 3 trial by December 31, 2025.

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Upon entering into the MEE License, we made a \$20 thousand license fee payment. We are obligated to pay certain annual license maintenance fees between \$5 thousand and \$7.5 thousand per each MEE patent family case number included in the licensed MEE patent rights prior to first commercial sale of an MEE licensed product. We are also obligated to pay a minimum annual royalty payment of \$15 thousand per each MEE patent family case number included in the licensed MEE patent rights prior to first commercial sale of an MEE licensed product. We are also obligated to make milestone payments up to \$350 thousand on each product or process that incorporate the licensed patent rights. In addition, we have agreed to pay a low single-digit royalty on products and processes that incorporate the licensed patent rights.

The Scripps Research Institute (California Institute for Biomedical Research)

In September 2018, we entered into a license agreement, or the CALIBR License, with the California Institute for Biomedical Research, or CALIBR, a division of The Scripps Research Institute, under which we received an exclusive, worldwide, royalty-bearing license to certain patent rights to make, have made, use, sell, offer to sell, and import products, or the CALIBR licensed products, which incorporate licensed technology for the treatment of MS. We have agreed to use commercially reasonable efforts to develop, manufacture, and sell at least one CALIBR licensed product. We are also subject to certain milestone timeline obligations, which may be extended in certain circumstances as described in the CALIBR License. In October 2021, we entered into an amendment with CALIBR which updated the milestone obligations to: (i) initiate a Phase 2 clinical trial (or equivalent) for a CALIBR licensed product by December 31, 2023 and (ii) initiate a Phase 3 clinical trial (or equivalent) for a CALIBR licensed product by December 31, 2025.

Upon entering into the CALIBR License, we made a \$1.0 million license fee payment, and are required to make milestone payments in an aggregate amount of up to \$26.0 million for each category of CALIBR licensed products. Category 1 is any CALIBR licensed products containing a compound that modulates any muscarinic receptor, and Category 2 is any CALIBR licensed products not included in Category 1 that could differentiate oligodendrocyte precursor cells from *in vitro* studies and/or active in animal models relevant to MS. We are also required to pay a mid-single-digit royalty on CALIBR licensed products and a royalty on sub-license revenues ranging from a low-teen percentage to 50%.

Components of our results of operations

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from product sales in the foreseeable future. In July 2019, we entered into the Astellas Agreement and received an upfront license fee payment of \$80.0 million. In accordance with ASC 606, we recognized the \$80.0 million as revenue over the period that research and development services for the Phase 2a clinical study for FX-322 (FX-322-202) were being provided using the input method. These research and development services concluded in June 2021. As such, \$14.1 million of the \$80.0 million upfront fee was recognized as revenue in the year ended December 31, 2021. No revenue was recognized in the year ended December 31, 2022.

Research and development expenses

Research and development expenses presented in this section consist primarily of costs related to activities largely focused on hearing restoration and MS. The following expenses include the following:

- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development function
- expenses incurred under agreements with third parties, including contract research organizations, or CROs, and other third parties that conduct preclinical

and development activities and clinical trials on our behalf;

- costs to manufacture our clinical trial material for use in our preclinical studies and clinical trials;
- costs of outside consultants, including their fees and related travel expenses;
- costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- option and license payments made to third parties, including MIT, Scripps, and MEE for intellectual property used in research and development activities

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- facility-related expenses, which include direct depreciation costs and expenses for rent and maintenance of facilities and other operating costs if specifically identifiable to research activities.

We track external research and development costs, candidates, including the cost of services, outsourced research and development, clinical trials, contract manufacturing, laboratory equipment and maintenance, and certain other development costs, by product candidate when the costs are specifically identifiable to a product candidate. Internal and external costs associated with infrastructure resources, other research and development costs, facility-related costs, and depreciation and amortization that are not identifiable to a specific product candidate are included in the platform development, early-stage research, and unallocated expenses category.

We cannot determine with certainty the duration and costs of future clinical trials of any product candidate we may develop or if, when, or to what extent we will generate revenue from the commercialization and sale of any product candidate for which we obtain marketing approval. The duration, costs, and timing of clinical trial development of any product candidate we may develop will depend on a variety of factors, including uncertainty of:

- the scope, rate of progress, expense and results expenses of our ongoing research activities as well as any preclinical studies, clinical trials of product and other research and development activities that we may conduct; activities;
- the actual probability establishing an appropriate safety profile with IND enabling studies;
- successful enrollment in and completion of success clinical trials;
- whether our product candidates show safety and efficacy in our clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates, including their safety and efficacy, efficacy, data, competition, manufacturing capability, and commercial viability; candidates;
- significant and changing government regulation and regulatory guidance;
- the timing and receipt of any marketing approvals;
- the progress of the development efforts of parties with whom we may enter into collaboration agreements;
- our ability to secure manufacturing supply through relationships with third parties;
- the commercialization of our commercializing product candidates, if and when approved;
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; approved, whether alone or in collaboration with others; and
- the impact continued acceptable safety profile of public health emergencies, such as COVID-19, on our ongoing and planned trials, products following regulatory approval.

A change Any changes in the outcome of any of these variables with respect to the development of a our product candidate candidates in preclinical and clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials for some product candidates or focus on other product candidates. For example, if the U.S. Food and Drug Administration, or FDA, European Medicines Agency, or EMA or another regulatory authority were to delay the planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect, we experience significant delays in enrollment in any planned clinical trial, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate.

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General and administrative expenses

Administrative Expenses

General and administrative expenses consist primarily of employee related costs, including salaries, bonuses, benefits, stock-based compensation and other compensation costs including stock-based compensation, for personnel in our executive finance, business development, and administrative functions. General and administrative

expenses also include legal fees relating to intellectual property and corporate matters; professional fees for services, including legal, accounting, auditing, tax service other consulting services; fees. General and administrative expenses also include facility costs not otherwise included in research and development expenses.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates. We also anticipate that we will incur significantly increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations costs; insurance costs; travel expenses; and facility-related expenses which include direct depreciation costs and expenses for rent and maintenance of facilities, and other associated with operating costs that are not specifically attributable to research and development activities of a public company.

Interest income

Interest income consists of interest earned on cash equivalents and marketable securities.

Interest expense

Interest expense consists of interest paid on our term loan.

Realized gain (loss) on investments

Realized gain (loss) on investments represents the gain or loss realized on our marketable securities.

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Foreign exchange (loss) gain

Foreign exchange (loss) gain represents the loss or gain recorded as a result of remeasuring the financial statements of our foreign subsidiaries.

Other Income, Net

Other income, (expense), net

Other income (expense), net primarily consists of amortization expense and accretion interest income earned on investments as well as sublease income.

Income taxes

Since our inception in 2014, we have generated cumulative federal and state net operating loss and research and development credit carryforwards for which we have not recorded any net tax benefit due to uncertainty around utilizing these tax attributes within the respective carryforward periods.

As of December 31, 2022, we had federal net operating loss carryforwards of approximately \$174.1 million and Massachusetts net state operating loss carryforwards of approximately \$141.3 million which may be available to offset future taxable income. The U.S. federal net operating loss carryforwards include \$22.4 million available to reduce future taxable income through 2037 and approximately \$151.7 million which do not expire and are available to reduce future taxable income indefinitely. The state net operating loss carryforwards are available to offset future taxable income through 2042. As of December 31, 2022, we also had federal and Massachusetts research and development tax credit carryforwards of \$8.2 million and \$3.6 million, respectively, which are available to offset federal and state tax liabilities through 2020 and 2037, respectively. Realization of future tax benefits is dependent on many factors, including our ability to generate taxable income within the net operating loss carryforward period. Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership of significant shareholders over a three-year period in excess of 50%, as provided under Sections 382 and 383 of the Code, respectively, as well as similar state provisions. These ownership changes may limit the number of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change as defined by Section 382 of the Code, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a rolling three-year period. We have completed several financings and have conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception and have determined that an ownership change did occur in March 2017. Accordingly, utilization of \$12.4 million of the U.S. net operating loss carryforwards which were incurred prior to March 2017 (pre-ownership change) is limited under Section 382 of the Code. As a result of the ownership change, the limitations under Section 382 of the Code, we may utilize approximately \$10.8 million of its pre-ownership change net operating loss carryforwards based upon an annual usage of approximately \$1.6 million for each of the next five years after the ownership change and approximately \$0.2 million for each of the 15 years thereafter. The remaining pre-March 2017 ownership change net operating losses of approximately \$1.6 million were written off due to expiration under limitation. The limitation has been determined by first multiplying the value of our stock at the time of the ownership change by the applicable long-term tax-exempt rate. These carryforwards may be subject to further annual limitations under Section 382 of the Code in the event of future changes in ownership. Additionally, we have determined an ownership change occurred in October of 2019 as a result of the IPO. Accordingly, utilization of approximately \$46.1 million of the U.S. net operating loss carryforwards incurred prior to October 2019 is also limited under Section 382 of the Code. We have determined it will be able to utilize the entire \$46.1 million of our pre-ownership change net operating loss carryforwards based upon the limitations calculated from the October 2019 ownership change. These carryforwards may be subject to further annual limitations under Section 382 of the Code in the event of future changes in ownership.

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money market fund accounts.

Results of operations

Operations

Comparison of years ended December 31, 2022 the Years Ended December 31, 2023 and 2021

2022

The following table summarizes our results of operations for the years ended **December 31, 2022**, **December 31, 2023** and **2021:2022**:

	Years ended December 31,	
	2022	2021
Revenue	\$ —	\$ 14.1
Operating expenses:		
Research and development	49,418	60,000
General and administrative	33,584	37,000
Total operating expenses	83,002	97,000
Loss from operations	(83,002)	(84,000)
Interest income	1,327	
Interest expense	(961)	
Realized gain (loss) on investments	3	
Foreign exchange (loss) gain	(5)	
Other income (expense), net	1,056	
Loss before income taxes	(81,582)	(84,000)
Tax benefit (provision)	2	
Net loss	\$ (81,580)	\$ (84,000)

(in thousands)	Year Ended December 31,		Change
	2023	2022	
Operating expenses:			
Research and development	\$ 57,250	\$ 42,201	\$ 15,049
General and administrative	27,284	16,797	10,487
Total operating expenses	84,534	58,998	25,536
Loss from operations	(84,534)	(58,998)	(25,536)
Other income, net			
Other income, net	3,389	976	2,413
Total other income, net	3,389	976	2,413
Loss before provision for income taxes	(81,145)	(58,022)	(23,123)
Provision for income taxes	27	10	17
Net loss	\$ (81,172)	\$ (58,032)	\$ (23,140)

Revenue

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2023 and 2022:

No revenue was recognized for the year ended December 31, 2022 compared to \$14.1 million for the year ended December 31, 2021. In July 2019, we entered the Astellas Agreement and received an upfront license fee payment of \$80.0 million. In accordance with ASC 606, we recognized the \$80.0 million as revenue over the period that research and development services were provided and the Phase 2a clinical study for FX-322 was carried out using the input method. These research and development services concluded in June 2021.

(in thousands)	Year Ended December 31,		Change
	2023	2022	
External research and development	\$ 18,683	\$ 13,868	\$ 4,815
Personnel-related expenses	15,298	9,960	5,338
Lab supplies & consumables	7,447	9,123	(1,676)
Facilities costs	9,252	4,588	4,664
Consulting	2,646	2,931	(285)
Sponsored research and license fees	2,104	376	1,728
Other	1,820	1,355	465

Total research and development expenses	\$ 57,250	\$ 42,201	\$ 15
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Research and development expenses

	Years ended December 31,		Increase
	2022	2021	(Decrease)
			(in thousands)
Direct research and development expenses by therapeutic area and product candidate:			
FX-322	\$ 10,855	\$ 10,334	\$
FX-345	4,217	5,471	(1)
Multiple Sclerosis	4,782	6,627	(1)
Platform development, early-stage research and unallocated expenses:			
Employee-related	20,015	25,557	(5)
Laboratory supplies	272	716	
Outsourced research and development	403	2,305	(1)
Facility-related	6,403	6,898	
Depreciation and amortization	1,618	1,599	
Other research and development	853	1,416	
Platform development, early-stage research and unallocated expenses total	29,564	38,491	(8)
Total research and development expenses	\$ 49,418	\$ 60,923	\$ (11)

The \$10.9 million of costs related to FX-322 incurred increased by \$15.0 million from \$42.2 million for the year ended December 31, 2022 consisted primarily of \$10.0 million of clinical costs associated with ongoing trials, including the recently completed Phase 2b clinical trial (FX-322-208), and \$0.6 million of drug development and manufacturing costs. The \$10.3 million of costs related to FX-322 incurred \$57.2 million for the year ended December 31, 2021 consisted December 31, 2023. The increase in research and development expenses was primarily of \$8.4 million of clinical costs associated with ongoing trials and \$1.9 million of drug development and manufacturing costs. The overall increase from the year ended December 31, 2021 is due primarily attributable to the FX-322-208 clinical trial activity in the year ended December 31, 2022, following:

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The \$4.8 million of costs related to MS incurred for the year ended December 31, 2022 consisted primarily of \$2.6 million of chemistry and compound characterization costs, \$0.7 million in drug development and manufacturing costs, \$0.6 million in preclinical safety costs, and \$0.4 million in *in vitro* sequencing expenses and *in vivo* testing costs. The \$6.6 million studies;

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- \$5.3 million of increased personnel-related expenses driven by an increase in headcount to support the expansion of our research and development footprint;
- \$1.7 million of decreased lab supplies and consumables, primarily attributable to reduction consumables purchased for screening and sequencing;
- \$4.7 million of increased facilities-related costs related primarily due to MS incurred for the year ended December 31, 2021 consisted expansion of \$3.1 million of mixed-use office spaces and depreciation of lab equipment;
- \$0.3 million decrease in preclinical safety consulting costs \$1.6 million attributed to the increase in chemistry and compound characterization costs, \$0.4 million in *in vitro* and *in vivo* testing costs, and \$0.8 million in drug development and manufacturing costs. The overall decrease from the year ended December 31, 2021 is primarily internal resources which led to a reduction in our reliance on external consulting services.;
- \$1.7 million of increased sponsored research and license fees primarily attributable to an upfront cash payment made to Genevant in March 2023 upon a collaboration and license agreement; and
- \$0.5 million of increased other expense primarily attributable to increased research and development software licensing fees and testing costs as we moved from exploratory activities to identification of specific proprietary compounds that act as lab maintenance services.

General and Administrative Expenses

The following table summarizes our novel target general and administrative expenses for remyelination in MS, the years ended December 31, 2023 and 2022:

The \$29.6 million of platform development, early-stage research and unallocated expenses incurred for the year ended December 31, 2022 consisted primarily of \$20.0 million in employee related costs, including \$7.7 million in stock-based compensation expense, \$6.4 million of facility-related costs, and \$1.6 million of depreciation expense. The decrease from the year ended December 31, 2021 is primarily attributable to a \$5.5 million decrease in employee-related expenses due predominantly to April 2022 reduction in force, a \$1.9 million decrease in outsourced research and development expenses as we decreased sponsored research, and a \$0.6 million decrease in other research and development expenses as we reduced our reliance on third-party consulting.

(in thousands)	Year Ended December 31,		Change
	2023	2022	
Personnel-related expenses	\$ 13,443	\$ 8,970	\$ 4,473
Professional services	8,507	4,529	3,978
Facilities expenses	3,253	1,600	1,653
Other	2,081	1,698	383
Total general and administrative expenses	\$ 27,284	\$ 16,797	\$ 10,487

General and administrative expenses

The \$33.6 million of general and administrative expenses increased by \$10.5 million from \$16.8 million for the year ended December 31, 2022 consisted primarily of \$20.6 million of employee-related costs, including \$12.1 million in stock-based compensation expense, \$5.6 million of professional services costs, \$2.7 million in directors' and officers' insurance costs, \$1.6 million in rent expense, including utilities and common area maintenance, or CAM, charges, and \$1.1 million in depreciation expense. General and administrative expenses decreased \$3.6 million from December 31, 2021 due to a \$2.1 million decrease in professional services costs as we reduced our reliance on third-party consulting and public relations vendors, a \$0.6 million decrease in directors' and officers' insurance costs, and a \$0.5 million decrease in employee-related costs due primarily to the April 2022 reduction in force.

Interest income

Interest income was \$1.3 million \$27.3 million for the year ended December 31, 2022 compared December 31, 2023. The increase in general and administrative expenses was primarily attributable to \$0.4 million for the year ended December 31, 2021, due following:

- \$4.5 million of increased personnel-related expenses is primary driven by \$2.5 million of severance cost to increases Frequency employees related to company regulation; The remaining increase of \$2.0 million is driven by an increase in interest rates from headcount to support growth in research and development and increased company regulation;
- \$4.0 million of increased professional service fees primarily attributable to recruiting efforts and increased intellectual property legal fees;
- \$1.7 million of increased facilities expenses primarily attributable to the previous year expansion of our mixed-use office space; and
- \$0.4 million of increased other general and administrative expense primarily attributable to increased software licensing fees and corporate expenses.

Interest expense Other Income, Net

Interest expense was Total other income, net increased by \$2.4 million from \$1.0 million for the year ended December 31, 2022 compared to \$0.8 million \$3.4 million for the year ended December 31, 2021, due December 31, 2023. The increase in other income, net was primarily attributable to increases an increase of \$2.4 million in interest rate income earned on our term loan money market fund accounts driven by rising interest rates and higher cash and cash equivalent balance.

Realized gain (loss) on investments103

Realized gain on investments was \$3 thousand for the year ended December 31, 2022 compared to a loss of \$23 thousand for the year ended December 31, 2021, due to changes in the composition of investments year over year.

Foreign exchange (loss) gain

Foreign exchange loss was \$5 thousand for the year ended December 31, 2022 compared to a gain of \$16 thousand for the year ended December 31, 2021. decrease was due to differences in foreign exchange remeasurement of the financial statements of our foreign subsidiaries.

Other income (expense), net

Other income, net was \$1.1 million for the year ended December 31, 2022 compared to expense of \$0.3 million for the year ended December 31, 2021. The change from the prior year is due to the inclusion of sublease income beginning in the third quarter of 2022.

Income taxes

Income tax benefit was \$2 thousand for the year ended December 31, 2022 compared to expense of \$15 thousand for the year ended December 31, 2021.

Liquidity and capital resources

Sources of Liquidity

Since our inception, we have generated recurring net losses. We have not yet commercialized any product and we do not expect to generate revenue from sales of any products for several years, if at all. Since inception, we have funded our operations primarily through proceeds from the issuance of convertible preferred stock and common stock. To date, we have raised approximately \$223.6 million of aggregate gross proceeds from the sale of convertible preferred stock and \$117.3 million from Pre-Closing Financing. As of December 31, 2023, we had cash and cash equivalents of \$166.1 million.

Since inception, we have incurred significant operating losses. As of December 31, 2023, we had an accumulated deficit of \$183.0 million. We expect to continue to incur significant expenses, and operating losses, and negative operating cash flows for the foreseeable future. In addition, we have not yet commercialized any product and we do not expect to generate revenue from sales of our product candidates for several years, if at all.

As of December 31, 2023, we had cash and cash equivalents of \$166.1 million. We expect that our research and development and general and administrative costs will continue to fluctuate, in connection with conducting preclinical studies and clinical trials for our product candidates, contracting with contract manufacturing organizations, or CMOs, to support preclinical studies and clinical trials, expanding our intellectual property portfolio, and providing general and administrative support for our operations. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources.

We do not currently have any approved products and have never generated any revenue from product sales. We have financed our operations primarily through proceeds from private and public securities financings, a term loan, and amounts received under a collaboration agreement. To date, we have raised approximately \$300 million, including from grants and option exercises. Our cash, cash equivalents and marketable securities totaled \$83.1 million as of December 31, 2022. As of December 31, 2023, we had \$10.0 million of current debt and \$4.2 million of non-current debt related to our term loan.

In December 2020, we entered into a Loan and Security Agreement with a commercial bank for a term loan with a principal balance of \$15.0 million. We made monthly interest only payments through November 30, 2022. The principal balance and interest will be repaid in equal monthly installments through May 1, 2024. Advances under the Loan Agreement will bear an interest rate equal to the greater of either (i) 1.50% plus the Prime Rate (as reported in *The Wall Street Journal*, subject to an interest rate floor of zero) or (ii) 4.75%.

In December 2021, we entered into an Equity Distribution Agreement with Oppenheimer & Co. Inc., or Oppenheimer, to sell shares of our common stock, having an aggregate offering price of up to \$125.0 million, from time to time, through an "at the market" equity offering program under which Oppenheimer will act as sales agent and/or principal, or the ATM Program. During the year ended December 31, 2022, we sold 12,767 shares of common stock under the ATM Program for net proceeds of approximately \$50 thousand and paid \$2 thousand to Oppenheimer in sales agent fees.

On April 8, 2022, we announced a reduction in force of approximately 30% of our workforce to better align our workforce with the needs of our business and focus more of our capital resources on our research and development programs. The total costs related to this reduction in force are approximately \$1.0 million in research and development expense and \$0.2 million in general and administrative expense, primarily related to severance costs and related expenses.

On February 13, 2023, we announced a restructuring that included downsizing personnel by approximately 55%. These changes are expected to preserve capital and ensure that we are appropriately resourced to complete a first clinical trial of our MS Program in the second half of 2024. The total costs related to this downsizing are approximately \$2.3 million in research and development expense and \$1.7 million in general and administrative expense, primarily related to severance costs and related expenses.

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Cash flows

The following table summarizes our sources and uses of cash for the periods presented:

	Year Ended	
	December 31,	
	2022	2021
	(in thousands)	
Net cash used in operating activities	\$ (58,237)	\$ (76,000)
Net cash provided by (used in) investing activities	31,133	(66,100)
Net cash (used in) provided by financing activities	(577)	1,300
Net decrease in cash and cash equivalents	\$ (27,681)	\$ (140,800)

Cash flows for the year ended December 31, 2022

Operating activities

Net cash used in operating activities for the year ended December 31, 2022 was \$58.2 million, consisting of a net loss of \$81.6 million. The net loss was partially offset by non-cash items related to normal business operations including stock-based compensation expense of \$19.8 million, depreciation expense of \$2.8 million, net cash lease expense of \$2.4 million and non-cash interest expense of \$0.4 million. Net cash used in operating activities was also impacted by a net \$2.0 million decrease in operating assets and liabilities, primarily the result of the continued reduction of lease liabilities over the term of the our leased office space.

The decrease in net cash used in operating activities for the year ended December 31, 2022 compared to the year ended December 31, 2021 is primarily due to changes in operating assets and liabilities year over year. Specifically, deferred revenue decreased \$14.1 million in the year ended December 31, 2021 due to the recognition of revenue related to the Astellas Agreement. No such decrease occurred in the year ended December 31, 2022. The decrease from December 31, 2021 is partially due to a \$3.1 million decrease in net loss.

Investing activities

Net cash provided by investing activities for the year ended December 31, 2022 was \$31.1 million, which was attributable to \$85.3 million in redemptions of marketable securities and \$17 thousand in sales of property and equipment partially offset by \$54.2 million of purchases of marketable securities.

The increase in net cash provided by investing activities for the year ended December 31, 2022 compared to the year ended December 31, 2021 is primarily due to a \$56.1 million increase in the redemption of marketable securities and a \$38.2 million decrease in the purchase of marketable securities. The increase is also due to a \$1.1 million decrease in purchases of property and equipment from the year ended December 31, 2021 as we furnished our new office and laboratory space in 2021 and did not incur such expenditures in 2022.

Financing activities

Net cash used in financing activities for the year ended December 31, 2022 was \$0.6 million, primarily attributable to \$0.8 million in term loan repayments partially offset by \$0.2 million in proceeds from the Employee Stock Purchase Plan and \$60 thousand in proceeds from the issuance of common stock under the ATM exercises of common stock.

The increase in net cash used in financing activities for the year ended December 31, 2022 compared to December 31, 2021 is primarily attributable to the million decrease in proceeds from the issuance of common stock. Additionally, we began making principle repayments on our term loan in the year ended December 31, 2022.

Cash flows for the year ended December 31, 2021

Operating activities

Net cash used in operating activities for the year ended December 31, 2021 was \$76.1 million, consisting of a net loss of \$84.7 million. The net loss was partially offset by non-cash items related to normal business operations including stock-based compensation expense of \$21.8 million, depreciation expense of \$2.8 million, net cash lease expense of \$1.1 million and non-cash interest expense of \$0.4 million. Net cash used in operating activities was also impacted by a net \$17.3 million decrease in operating assets and liabilities, primarily due to the \$14.1 million reduction in deferred revenue as all remaining

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revenue related to the Astellas Agreement was recognized in the year ended December 31, 2021 as well as a \$2.3 million decrease in accounts payable due to the timing of invoice receipt and payment.

Investing activities

Net cash used in investing activities for the year ended December 31, 2021 was \$66.1 million, which was attributable to \$92.4 million of purchases of marketable securities and \$2.9 million of purchases of property and equipment, partially offset by \$29.2 million in redemptions of marketable securities.

Financing activities

Net cash provided by financing activities for the year ended December 31, 2021 was \$1.4 million, primarily attributable to \$1.3 million in proceeds from the exercise of stock options and \$60 thousand in proceeds from the Employee Stock Purchase Plan.

Funding requirements

We expect our future operating expenses to reflect our ongoing research and development for our MS Program, preclinical activities, studies for INDs, and initiation of clinical trials. In addition, we expect to maintain general and administrative costs to manage the requirements of operating as a public company.

Specifically, our costs and expenses will increase as we:

- pursue the preclinical and clinical development of a candidate for remyelination in MS and any other product candidates using our PCA approach; and
- maintain, expand, and protect our intellectual property portfolio.

We believe that our existing cash, cash equivalents, and marketable securities, will enable us sufficient to fund our operating expenses and capital expenditure requirements into 2025, 2026. We have based this estimate on assumptions that may prove to be incorrect, wrong, and we could utilize expend our available capital resources sooner than we expect. We may also pursue additional cash resources through public or private equity, collaborations or debt financings. There is no assurance that we will be successful in obtaining sufficient financing on acceptable terms to continue funding our operations.

Funding Requirements

We expect to continue to incur significant expenses, operating losses, and negative operating cash flows for the foreseeable future as we continue our novel gene and cell therapy discovery efforts, advance our pipeline candidates into the clinic and through clinical trials, seek regulatory approval of our product candidates and pursue commercialization of any approved product candidates. In addition, we expect to continue to incur costs associated with operating as a public company.

Because of the numerous risks and uncertainties associated with the research, development and commercialization of therapeutics, it is difficult our product candidates, we are unable to estimate with certainty the exact amount of our working capital requirements.

Our future funding capital requirements will depend on many factors, including:

- the cost of continuing to build our OPERA platform and discover additional novel genetic medicines;
- the scope, progress, results, and costs and results of our research and discovery, preclinical development, program laboratory testing, manufacturing a trials for remyelination in MS; the product candidates we may develop;
- the extent to which we partner our programs, acquires or in-licenses other product candidates and technologies or enters into additional collaborations
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, EMA and comparable foreign other regulatory authorities, if our product candidates;
- business and operations interruptions resulting from public health emergencies, such as the COVID-19 global pandemic; authorities;
- the costs timing and timing amount of internal process development, manufacturing activities, milestone and clinical trial management associated with product candidates royalty payments that we advance through preclinical are required to make or eligible to receive under any future collaboration and clinical trial
- our ability to establish and maintain strategic collaborations, licensing or other agreements and the financial terms of such license agreements;
- the scope, progress, results, Our headcount growth and associated costs of any product candidates that as we may derive from expand our PCA approach other product candidates we may develop alone or with collaborators; research and development efforts;
- the extent to which we in-license or acquire rights to cost of expanding, maintaining and enforcing our intellectual property portfolio, including filing, prosecuting, defending and enforcing our patent claims and other products, product candidates, or technologies;
- additions or departures of key scientific or management personnel; intellectual property rights;
- the costs and timing cost of preparing, filing, and prosecuting patent applications, maintaining and protecting our defending potential intellectual property defending disputes, including patent infringement actions brought by third parties against us or any intellectual property-related claims; and of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any product candidate we or our collaborators obtain receive marketing approval. approval;
- the cost and timing of completion of commercial-scale manufacturing activities;
- the effect of competing technological and market developments; and
- the costs of operating as a public company.

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Until such time, if ever, as we can generate significant revenue from substantial product sales, if ever, revenues to support our cost structure, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, collaborations and other sources, which may include current and new collaborations with third parties, similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a of our common stockholder. stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, or other sources, such as collaboration agreements, strategic alliances, licensing similar arrangements or marketing and distribution arrangements, with parties, we may have to relinquish valuable rights to our technologies, future revenue streams, product development, and research programs or product candidates or licenses on terms that may not be favorable to us, us and/or may reduce the value of our common shares. If we are unable to raise additional funds through equity or financings when needed, we may be required to delay, limit, reduce or terminate our product research and development or future commercialization efforts or grant rights to develop and market products or our product candidates that even if we would otherwise prefer to develop and market such product candidates ourselves.

Cash Flows

Comparison of the Years Ended December 31, 2023 and 2022

The following table summarizes our cash flows for the years ended December 31, 2023 and 2022:

Contractual obligations and commitments

	Year Ended December 31,

(in thousands)	2023	2022
Net cash used in operating activities	\$ (67,283)	\$ (53,611)
Net cash provided by investing activities	11,164	11,000
Net cash provided by financing activities	187,761	187,761
Net increase (decrease) in cash, cash equivalents and restricted cash	\$ 131,642	\$ (42,511)

We are party Cash Used in Operating Activities

Net cash used in operating activities for the year ended December 31, 2023 was \$67.3 million, compared to an net cash used in operating lease activities of approximately 61,307 square feet \$53.6 million for the year ended December 31, 2022. The increase of office and laboratory space \$13.7 million in Lexington, Massachusetts with a term through May 31, 2031. Pursuant cash used in operating activities was primarily due to this lease, we have provided a security deposit of \$1 million which is classified as restricted cash as of December 31, 2022. As of December 31, 2022, the overall increase in our operating lease obligations under this lease \$40.2 million. See Note 14, "Leases", expenses during that same period, including an increase in payments made for additional information regarding this lease, external research and development activities.

Cash Provided by Investing Activities

Payment obligations Net cash provided by investing activities for future milestone payments under our collaboration the year ended December 31, 2023 was \$ million, compared to net cash provided by investing activities of \$11.0 million for the year ended December 31, 2022. Net cash provided by investing activities primarily consists of proceeds from maturities of investments partially offset by cash used to purchase property and license agreements are contingent upon future events, such as the achievement of specified product development milestones or generating product sales, and we are unable to estimate the timing or likelihood of achieving these milestones or generating future product sales. We were also required to use diligent efforts to develop and commercialize the MIT licensed products or processes, and make such products or processes reasonably available to the public under the MIT License. See "—License and collaboration agreements" for more information regarding our payment obligations under these agreements, equipment.

Cash Provided by Financing Activities

We also enter into contracts Net cash provided by financing activities for the year ended December 31, 2023 was \$187.8 million, compared to less than \$0.1 million for the year ended December 31, 2022. The increase of \$187.8 million in cash provided by financing activities is primarily due to \$117.3 million of gross proceeds from normal course Pre-Closing Financing, \$45.5 million of business with CROs, CMOs, universities, net cash proceeds received from the sale of Legacy Korro's Series B-1 convertible preferred stock and other third parties for preclinical research studies, clinical trials and testing and manufacturing services. These contracts generally do not contain minimum purchase commitments and are cancelable by us upon prior written notice although, purchase orders for clinical materials are generally non-cancelable. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including non-cancelable obligations of our service providers, until the date of cancellation or upon \$24.4 million net cash acquired from completion of the Merger, which was accounted for as a manufacturing run. The amount and timing of such payments are not known or are not material. reverse recapitalization. No comparable proceeds were received from financing activities during the year ended December 31, 2022.

Critical accounting policies Accounting Policies and use of estimates

Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our audited consolidated financial statements which have been prepared in accordance with generally accepted accounting principles generally accepted in the United States. The preparation of our these consolidated financial statements and related disclosures requires us to make estimates judgments and assumptions estimates that affect the reported amounts of assets, and liabilities, revenues costs revenues and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimate in changes in circumstances, facts, and experience. The effects of material

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revisions in estimates, if any, will be reflected in the consolidated financial statements prospectively from the date of change in estimates.

While our significant accounting policies are described in more detail in the notes Note 2 to our audited consolidated financial statements included appearing elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue recognition

We account for contracts with customers in accordance with Accounting Standards Codification (ASC), Topic 606, *Revenue from Contracts with Customers* (ASC 606), including all amendments thereto. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as collaborative arrangements Accrued and leases. Our disclosure in the accompanying consolidated financial statements reflects the Company's accounting policies in compliance with this standard.

Under ASC 606, an entity recognizes revenue when or as its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To recognize revenue for arrangements that an entity determines are within the scope of ASC 606, the entity performs the

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following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; Prepaid Research and (v) recognize revenue when (or as) the entity satisfies its performance obligations. We only apply the five-step model to contracts when it is probable that the entity will collect substantially all of the consideration to which it will be entitled in exchange for the goods or services it transfers to the customer. Once a contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and identifies as a performance obligation each promise to transfer to the customer either (a) a good or service (or bundle of goods and services) that is distinct, or (b) a series of distinct goods and services that are substantially the same and have been the same pattern of transfer to the customer.

We assess whether each promised good or service is distinct for the purpose of identifying the performance obligations in the contract. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services and whether such are separable from the other aspects of the contractual relationship. Promised goods and services are considered distinct provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct) and (ii) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract). In assessing whether a promised good or service is distinct, we consider factors such as the research, manufacturing and commercialization capabilities of the collaboration partner (the "customer" in this type of arrangement) and the availability of the associated expertise in the general marketplace. We also consider the intended benefit of the contract in assessing whether a promised good or service is separately identifiable from other promises in the contract. If a promised good or service is not distinct, an entity is required to combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct. For each arrangement that results in revenues, we identify all performance obligations, which may include, for example, a license to IP and know-how, research and development activities, and/or manufacturing services.

In addition to any upfront payment, if the consideration promised in a contract includes a variable amount, we estimate the amount of consideration to which it is entitled in exchange for transferring the promised goods or services to a customer. We determine the amount of variable consideration by using the expected value method or the most likely amount method. We include the estimated variable consideration in the transaction price to the extent it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, we re-evaluate the estimated variable consideration included in the transaction price for any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment.

If an arrangement includes development and regulatory milestone payments, we evaluate whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. If it is probable that a significant revenue reversal will not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or of the licensee such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

For contracts that include sales-based royalties (including milestone payments based on the level of sales) promised in the exchange for licenses of intellectual property, and the license is deemed to be the predominant item to which the royalties relate, we recognize royalty revenue and sales-based milestone payments at the time of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied. In determining the transaction price, we adjust the promised amount of consideration for the effects of the time value of money if the timing of payments provides the Company or the Company's customer with a significant benefit of financing the transfer of goods and services. We do not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less. We assess each of its revenue generating arrangements in order to determine whether a significant financing component exists. We recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied, either at a point in time or over time. For performance obligations satisfied over time, we measure progress toward completion of its performance obligations using an input method based on our efforts and inputs to satisfy its performance obligations relative to total expected inputs to the satisfaction of that performance obligation.

Amounts received from a customer prior to revenue recognition are recorded as deferred revenue. Amounts received from a customer that are expected to be recognized as revenue within the 12 months following the balance sheet date are classified as a current liability in the consolidated balance sheets.

Our only revenue recognized since inception is related to the Astellas Agreement. At commencement of the Astellas Agreement, we estimated the performance obligation, the completion of the Phase 2a clinical trial of (FX-322-202), would be satisfied by June 30, 2021. Consistent with our estimate, the performance obligation was satisfied in June 2021.

Accrued research and development expenses

Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. The process involves reviewing open contracts and purchase orders, communicating with our internal personnel to identify services that have been performed on our behalf, estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. Most of the majority of our service providers require advance payments; however, some providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. Examples We periodically confirm the accuracy of our estimated accrued research and development expenses with the service providers and make adjustments if necessary.

We recognize expenses include fees paid related to the following:

- CROs and other third parties in connection with performing research and development activities and conducting preclinical studies and clinical trials or
- Vendors in connection with preclinical development activities; and
- CMOs and other vendors in connection with product manufacturing and development and distribution of preclinical supplies.

We base our expenses related to preclinical studies on our estimates of the services received and efforts expended pursuant to quotes and contracts with CROs, research institutions and clinical research organizations that conduct and manage preclinical studies and clinical trials and CMOs that manufacture product for our research and development activities on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or amount of prepaid expense accordingly. Although we expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may cause us to report amounts that are too high or too low in any particular period. To date, we have made any material adjustments to our prior estimates of accrued research and development expenses.

Contractual Obligations and Other Commitments

Stock-based compensation Our contractual obligations and commitments relate primarily to our operating leases and non-cancelable purchase obligations under agreements with various research and development organizations and suppliers in the ordinary course of business. See Note 14, "Commitments and Contingencies" in our audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Recent Accounting Pronouncements

A description of recently issued and recently adopted accounting pronouncements applicable to our financial position and results of operations is included in Note 2 to our audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Emerging Growth Company and Smaller Reporting Company Status

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. We may take advantage of these exemptions until we are no longer an emerging growth company under Section 107 of the JOBS Act, which provides that an emerging growth company can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. We have elected to avail ourselves of the extended transition period and, therefore, while we are an emerging growth company, we will not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not emerging growth companies, unless we choose to early adopt a new or revised accounting standard. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering, (b) which we have total annual gross revenue of at least \$1.235 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by

non-affiliates exceeds \$700 million as of the prior June 30th, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior t year period.

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the la of the fiscal year in which (i) the market value of our common stock held by non-affiliates exceeds \$250 million as of the prior June 30, or (ii) our annual revenues exce \$100 million during such completed fiscal year and the market value of our common stock held by non-affiliates exceeds \$700 million as of the prior June 30.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

As of December 31, 2023, we had cash and cash equivalents of \$166.1 million, which consist of bank deposits and money market funds. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, an immediate 10% change in market interest rates would n have a material effect on the fair market value of our cash or cash equivalents.

Our employees and operations are primarily located in the United States. We have, from time to time, engaged in contracts with contractors or other vend currency other than the U.S. dollar. To date, we have had minimal exposure to fluctuations in foreign currency exchange rates as the time period between the date tha transactions are initiated, and the date of payment or receipt of payment is generally of short duration. Accordingly, we believe it does not have a material exposure to foreign currency risk.

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Item 8. Financial Statements and Supplementary Data

Korro Bio, Inc

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Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Korro Bio, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Korro Bio, Inc. (the Company) as of December 31, 2023 and 2022, the related consolidated state of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the two years in the period ended Dec 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements ba on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be

independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We **measure** have served as the Company's auditor since 2020.
Boston, Massachusetts
March 26, 2024

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Korro Bio, Inc.		
Consolidated Balance Sheets		
(amounts in thousands, except share and par value amounts)		
	December 31,	
	2023	2022
Assets:		
Current assets:		
Cash and cash equivalents	\$ 166,150	\$ 3
Short-term investments	—	1
Restricted cash	3,563	
Prepaid expenses and other current assets	3,015	
Total current assets	172,728	5
Property and equipment, net	15,665	
Operating lease right-of-use assets	27,150	
Restricted Cash, net of current portion	3,406	
Other non-current assets	2,714	
Total assets	\$ 221,663	\$ 7
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 7,280	\$
Accrued expenses and other current liabilities	10,212	
Operating lease liabilities, current portion	1,991	
Total current liabilities	19,483	
Operating lease liabilities, net of current portion	31,216	
Other non-current liabilities	1,053	
Total liabilities	51,752	
Commitments and contingencies (Note 13)		
Series Seed convertible preferred stock, \$0.001 par value; no shares and 684,739 shares authorized, issued and outstanding at December 31, 2023 and 2022 (aggregate liquidation preference of \$0 and \$16,115 at December 31, 2023 and 2022)	—	1

Series A convertible preferred stock, \$0.001 par value; no shares and 2,029,666 shares authorized, issued and outstanding at December 31, 2023 and 2022 (aggregate liquidation preference of \$0 and \$91,500 at December 31, 2023 and 2022)	—	7
Series B-1 convertible preferred stock, \$0.001 par value; no shares and 1,104,178 shares authorized, issued and outstanding at December 31, 2023 and 2022 (aggregate liquidation preference of \$0 and \$58,000 at December 31, 2023 and 2022)	—	5
Series B-2 convertible preferred stock, \$0.001 par value; no shares and 1,036,656 shares authorized at December 31, 2023 and 2022; no shares and 223,417 shares issued and outstanding at December 31, 2023 and 2022 (aggregate liquidation preference of \$0 and \$12,500 at December 31, 2023 and 2022)	—	1
Stockholders' equity (deficit)		
Preferred stock, \$0.001 par value; 10,000,000 shares and no shares authorized at December 31, 2023 and 2022; no shares issued and outstanding at December 31, 2023 and 2022	—	
Common stock, \$0.001 par value; 200,000,000 and 5,755,759 shares authorized at December 31, 2023 and 2022; 8,016,516 and 271,371 shares issued at December 31, 2023 and 2022, respectively; 8,016,516 and 268,468 shares outstanding at December 31, 2023 and 2022	8	
Additional paid-in capital	352,908	
Accumulated other comprehensive loss	—	
Accumulated deficit	(183,005)	(10)
Total stockholders' equity (deficit)	169,911	(9)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	\$ 221,663	\$ 7

The accompanying notes are an integral part of these consolidated financial statements.

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Korro Bio, Inc.

Consolidated Statements of Operations and Comprehensive Loss

(amounts in thousands, except share and per share amounts)

	Years Ended December 31,	
	2023	2022
Operating expenses:		
Research and development	\$ 57,250	\$ 42,200
General and administrative	27,284	16,700
Total operating expenses	84,534	58,900
Loss from operations	(84,534)	(58,900)
Other income:		
Other income, net	3,389	900
Total other income, net	3,389	900
Loss before provision for income taxes	(81,145)	(58,000)
Provision for income taxes	27	—
Net loss	\$ (81,172)	\$ (58,000)
Other comprehensive income		
Unrealized gain on available-for-sale investments	—	—
Comprehensive loss	\$ (81,172)	\$ (58,000)
Net loss per share, basic and diluted	\$ (53.08)	\$ (227.00)
Weighted-average shares used in computing net loss per share, basic and diluted	1,529,321	255,100

The accompanying notes are an integral part of these consolidated financial statements.

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Korro Bio, Inc.

Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

(amounts in thousands, except share amounts)

									Accumulated									
	Series Seed		Series A		Series B-1		Series B-2		Common Stock		Additional Paid-In Capital		Other Comprehensive Loss		Accumulated Deficit		Total Stockholders' Equity (Deficit)	
	Convertible Preferred Stock		Convertible Preferred Stock		Convertible Preferred Stock		Convertible Preferred Stock											
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	In Capital	Loss	Deficit	Deficit				
Balance at December 31, 2021		15,92		77,73		57,7		12,50										
2021	684,739	\$ 4	2,029,666	\$ 6	1,104,178	\$ 03	223,417	\$ 0	237,803	—	\$ 1,600	\$ (7)	\$ (43,801)	\$				
Issuance of common stock for services rendered	—	—	—	—	—	—	—	—	497	—	11	—	—	—				
Exercises of stock options	—	—	—	—	—	—	—	—	8,722	—	62	—	—	—				
Vesting of restricted common stock	—	—	—	—	—	—	—	—	21,377	—	5	—	—	—				
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	1,129	—	—	—				
Other comprehensive income	—	—	—	—	—	—	—	—	—	—	—	2	—	—				
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(58,032)	—				
Balance at December 31, 2022		15,92		77,73		57,7		12,50										
2022	684,739	\$ 4	2,029,666	\$ 6	1,104,178	\$ 03	223,417	\$ 0	268,399	—	\$ 2,807	\$ (5)	\$ (101,833)	\$				
Issuance of Series B-2 convertible preferred stock, net of issuance costs	—	—	—	—	—	—	813,239	45,458	—	—	—	—	—	—				
Issuance of common stock for services rendered	—	—	—	—	—	—	—	—	292	—	6	—	—	—				
Exercises of stock options	—	—	—	—	—	—	—	—	73,394	—	702	—	—	—				
Vesting of restricted common stock	—	—	—	—	—	—	—	—	2,902	—	—	—	—	—				
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	2,375	—	—	—				
Issuance of common stock for cash in PIPE financing	—	—	—	—	—	—	—	—	2,077,864	2	117,250	—	—	—				
Conversion of preferred stock to common stock	(684,739)	(15,924)	(2,029,666)	(77,736)	(1,104,178)	(57,703)	(1,036,656)	(57,958)	4,855,208	5	209,315	—	—	—				
Issuance of common stock to Frequency shareholders in reverse recapitalization	—	—	—	—	—	—	—	—	738,457	1	32,700	—	—	—				
Reverse recapitalization transaction costs	—	—	—	—	—	—	—	—	—	—	(12,247)	—	—	—				
Other comprehensive income	—	—	—	—	—	—	—	—	—	—	—	5	—	—				
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(81,172)	—				
Balance at December 31, 2023									8,016,516	\$ 8	\$ 352,908	—	\$ (183,005)	\$				
2023	—	—	—	—	—	—	—	—	6	—	\$ 352,908	—	\$ (183,005)	\$				

The accompanying notes are an integral part of these consolidated financial statements.

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Korro Bio, Inc.
Consolidated Statements of Cash Flows
(amounts in thousands)

	Years Ended December 31,	
	2023	2022
Operating Activities:		
Net loss	\$ (81,172)	\$ (58,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash lease expense	3,610	1,300
Stock-based compensation expense	2,381	1,100
Depreciation expense	3,630	2,500
Non-cash interest expense	—	100
Net amortization of premiums and discounts on investments	(80)	(100)
Loss on disposal of property and equipment	65	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	559	(600)
Accounts payable	3,100	1,700
Accrued expenses	1,270	(600)
Operating lease liabilities	1,341	(2,100)
Other non-current assets	(1,987)	(100)
Net cash used in operating activities	(67,283)	(53,600)
Investing Activities:		
Purchases of investments	—	(37,200)
Proceeds from maturities of investments	19,000	53,400
Purchases of property and equipment	(7,836)	(5,100)
Advance payments for property and equipment not yet received	—	(600)
Net cash provided by investing activities	11,164	11,000
Financing Activities:		
Proceeds from Series B-2 convertible preferred stock, net of issuance costs	45,458	—
Proceeds from exercises of stock options	702	—
Proceeds from the issuance of common stock in pre-closing financing	117,250	—
Cash acquired in connection with the reverse recapitalization	36,600	—
Payment of reverse recapitalization transaction costs	(12,247)	—
Other financing activities, net	(2)	(600)
Net cash provided by financing activities	187,761	—
Net increase (decrease) in cash, cash equivalents and restricted cash	131,642	(42,500)
Cash, cash equivalents and restricted cash, beginning of period	41,477	84,000
Cash, cash equivalents and restricted cash, end of period	\$ 173,119	\$ 41,400
Non-cash investing and financing activities:		
Property and equipment capitalized under tenant improvement allowance	\$ 2,271	\$ —
Purchases of property and equipment in accounts payable and accrued expenses	\$ 1,983	\$ 400
Operating lease liabilities arising from right-of-use assets	\$ 26,777	\$ 5,600
Operating lease liabilities arising from lease modification	\$ 1,959	\$ —
Supplemental cash flow information:		
Cash paid for income taxes	\$ 27	\$ —
Cash paid for operating lease liabilities	\$ 2,978	\$ 2,300

The accompanying notes are an integral part of these consolidated financial statements.

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Korro Bio, Inc.

Notes to Consolidated Financial Statements

1. The Company and Liquidity

Nature of Business

Korro Bio, Inc. (together with its subsidiaries, the "Company") is a biopharmaceutical company with a mission to discover, develop and commercialize a new class of medicines based on editing RNA, enabling the treatment of both rare and highly prevalent diseases. The Company was incorporated in November 2014 as a Delaware corporation. The Company's principal offices are in Cambridge, Massachusetts.

Risks and Uncertainties

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing. Product candidates currently under development will require significant additional research and development efforts, including extensive pre-clinical and clinical testing and regulatory approval, prior to commercialization. These efforts will require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance-reporting capabilities. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from product sales.

Reverse Merger with Legacy Korro

On July 14, 2023, Frequency Merger Sub, Inc. ("Merger Sub") a Delaware corporation, a wholly-owned subsidiary of Frequency Therapeutics, Inc. ("Frequency"), a Delaware corporation and Korro Bio, Inc. ("Legacy Korro"), a Delaware corporation, entered into an Agreement and Plan of Merger (the "Merger Agreement"). The merger was completed on November 3, 2023 (the "Merger" or the "Transaction"). In accordance with the Merger Agreement, the Merger Sub merged with and into Legacy Korro, with Legacy Korro surviving as a wholly-owned subsidiary of the Company. In connection with the completion of the Merger, the Company changed its name from Frequency Therapeutics, Inc. to Korro Bio, Inc. On November 6, 2023, the combined company's common stock began trading on The Nasdaq Capital Market under the ticker symbol "KRRO".

Except as otherwise indicated, references herein to the "Company," or the "combined company", refer to Korro Bio, Inc. on a post-merger basis, and the term "Legacy Korro" refers to the business of privately held Korro Bio, Inc., prior to completion of the merger. References to Frequency refer to Frequency Therapeutics, Inc. prior to completion of the merger.

Concurrently with the execution and delivery of the Merger Agreement, Legacy Korro entered into a subscription agreement with a number of accredited investors. Immediately prior to consummation of the Merger, Legacy Korro issued and sold an aggregate of 42,176,255 shares of its common stock at a purchase price of approximately \$2.78 per share, for an aggregate purchase price of approximately \$117.3 million. Shares of Legacy Korro common stock issued pursuant to the Pre-Closing Financing were converted into shares of the Company's common stock based on an exchange ratio (as defined below).

Pursuant to the terms of the Merger Agreement, immediately prior to the effective time of the Merger, each share of Legacy Korro preferred stock was converted into one share of Legacy Korro common stock, and then exchanged in the Merger for shares of Frequency common stock using an exchange ratio of 0.049688 (the "Exchange Ratio").

At the effective time of the Merger, the Company issued (or reserved for issuance upon exercise of options assumed in the Merger) an aggregate of approximately 7,848,776 shares of its common stock to Legacy Korro securityholders (before eliminating fractions), calculated as provided in the Merger Agreement, (the "Exchange" resulting in approximately 8,623,645 shares of its common stock being issued and other stock-based outstanding on a fully diluted basis immediately following the effective time of the Merger. This number includes shares of the Company's common stock that was issued upon vesting and settlement of certain outstanding equity awards granted at the effective time of the Merger. Immediately following the completion of the Merger, Frequency securityholders prior to our employees, directors, consultants and advisors the Merger owned approximately 9% of the outstanding shares of common stock on a fully diluted basis and Legacy Korro's securityholders, including those securityholders who purchased shares in Legacy Korro's pre-closing financing, owned approximately 91% of the outstanding shares on a fully diluted basis. The Merger intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended (the "IRC").

Upon closing of the Merger, the Company assumed the Legacy Korro 2019 Stock Incentive Plan, and each outstanding and unexercised option to purchase Legacy Korro shares at such time, each of which converted into an option to purchase shares of the Company's common stock, with necessary adjustments to the number of shares and exercise price to reflect the Exchange Ratio. In addition, upon the closing of the Merger, the Company assumed each outstanding and unexercised warrant to purchase

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Legacy Korro shares at such time, each of which converted into a warrant to purchase shares of the Company's common stock, with necessary adjustments to the number of shares and exercise price to reflect the Exchange Ratio.

At the effective time of the Merger, the Company entered into a contingent value rights agreement (the "CVR Agreement") with Computershare Trust Company, N.A. a Computershare Inc., collectively as rights agent providing for the payment of certain contingent cash payments equal to the net amount (calculated in accordance with GAAP consistently applied) of proceeds actually received by the Company or its subsidiaries after the end of each fiscal quarter following the first anniversary of the closing of the Transaction related to the disposition of assets related to Frequency's former multiple sclerosis programs, with the time periods and subject to deductions as provided therein. Concurrently, the Company entered into an asset purchase agreement with Progentos Therapeutics ("Progentos"), whereby Progentos acquired the rights, title and interest in certain assets related to Frequency's MS program ("MS APA"). The MS APA included initial consideration of \$0.5 million in proceeds that were settled through cash at the merger closing and will be entitled to future milestone payments of up to \$17.5 million as well as a \$0.7 million payment in the event of Progentos closing its equity financing at or above a specified amount.

The Merger was accounted for as a reverse recapitalization in accordance with U.S. GAAP. For accounting purposes, Legacy Korro was considered to be acquiring the assets and liabilities of Frequency in the Merger based on the terms of the Merger Agreement and other factors, including: (i) Legacy Korro controlling the majority of outstanding voting shares; (ii) Legacy Korro controlling the Board of Directors; (iii) Legacy Korro's executive management team became the management of the combined company; and (iv) the pre-combination assets of Frequency were primarily cash and cash equivalents and other non-operating assets. Accordingly, the Merger was treated as the equivalent of Legacy Korro issuing stock to acquire the net assets of Frequency. As a result of Legacy Korro being treated as the accounting acquirer, Legacy Korro's assets and liabilities were recorded at their pre-combination carrying amounts. Frequency's assets and liabilities were measured and recognized at their fair values, which approximated their carrying values as of the effective date of the Merger, and combined with the assets, liabilities, and results of operations of Legacy Korro after the consummation of the Merger. As a result, upon consummation the historical financial statements of Legacy Korro became the historical consolidated financial statements of the combined company.

Reverse Stock Split and Exchange Ratio

In connection with, and prior to the completion of, the merger, Frequency effected a one-for-fifty reverse stock split of its then outstanding common stock (the "Reverse Stock Split"). The par value and the authorized shares of the common stock were not adjusted as a result of the Reverse Stock Split. All issued and outstanding Legacy Korro common stock, convertible preferred stock and options prior to the effective date of the merger have been retroactively adjusted to reflect the merger 0.049688 Exchange Ratio, which reflects the impact of the reverse stock split, for all periods presented.

Liquidity and Capital Resources

The Company's consolidated financial statements have been prepared on the basis of the Company continuing as a going concern. The Company expects that its existing cash and cash equivalents as of December 31, 2023 of \$166.1 million will enable the Company to fund its planned operating expense and capital expenditure requirements for at least twelve months from the date of issuance of these consolidated financial statements. The Company has incurred recurring losses and negative cash flows from operations since inception. As of December 31, 2023, the Company had an accumulated deficit of \$183.0 million. The Company expects its operating losses and negative operating cash flows to continue into the foreseeable future. The future viability of the Company is dependent on its ability to generate cash from operating activities or raise additional capital to finance its operations. There can be no assurance that the Company will ever earn revenues or achieve profitability, or if achieved, that the revenues or profitability will be sustained on a continuing basis. In addition, the Company's preclinical and clinical development activities, manufacturing and commercialization of the Company's product candidates, if approved, will require significant additional financing. However, if the Company is unable to obtain additional financing, the Company would be forced to delay, reduce or eliminate its research and development programs and/or relinquish valuable rights to its technology and product candidates. There is no assurance that the Company will be successful in obtaining sufficient financing on acceptable terms to continue funding its operations.

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2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP"). These consolidated financial statements have been prepared on the going concern basis of accounting, which assumes continuity of operations, realization of assets and satisfaction of liabilities in the ordinary course of business.

The consolidated financial statements include the accounts of Korro Bio, Inc. and its wholly-owned subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision-maker in deciding how to allocate resources and assess performance. The Company and the Company's chief operating decision maker, the Company's chief executive officer, views the Company's operations and manages its business as a single operating segment. The Company operates only in the United States.

Use of Estimates

The preparation of the Company's consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the grant, awards, net consolidated financial statements and the reported amounts of actual forfeitures, expenses during the reporting period. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the fair value of the common stock prior to the effective date of the merger; the fair value of the CVR liability and the incremental borrowing rate for determining lease liabilities and right-of-use assets. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it has concluded to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results may differ materially from those estimates or assumptions.

Fair Value of Financial Instruments

ASC Topic 820, *Fair Value Measurement*, ("ASC 820") establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances.

ASC 820 identifies fair value as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tier fair value hierarchy that distinguishes between the following:

- Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities.
 - Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.
 - Level 3 inputs are unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability.
- Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

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Cash Equivalents

Cash equivalents are highly-liquid investments that are readily convertible into cash with original maturities of three months or less when purchased. These assets include investments in money market funds that invest in U.S. Treasury obligations. Cash equivalents are reflected at fair value based on quoted market prices, as further described in Note 3, "Fair Value Measurements".

Investments

Investments consist of securities with original maturities greater than three months when purchased. Short-term investments consist of investments that are available for sale in current operations. Long-term investments consist of investments with maturities of greater than one year that are not available for use in current operations. The Company did not maintain any long-term investments as of December 31, 2023 or 2022.

The Company classifies all of its investments as available-for-sale securities. Accordingly, these investments are recorded at fair value. Realized gains and losses and amortization and accretion of discounts and premiums are included in "Other income, net". Unrealized gains and losses on available-for-sale securities are included in "Accumulated other comprehensive loss" as a component of stockholders' deficit until realized.

The Company reviews its investment portfolio to identify and evaluate investments that have indicators of possible other-than-temporary impairment. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition of the issuer, and the Company's intent to sell the investment or to hold it for a period of time sufficient to allow for recovery of its value.

issuer and the Company's intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value.

Property and Equipment

Property and equipment are recorded at cost and consists of laboratory equipment, furniture and office equipment, computer equipment, leasehold improvements, and construction in progress. The Company capitalizes property and equipment that is acquired for research and development activities and that has alternative future use. Expenditures for repairs and maintenance are recorded to expense as incurred, whereas major betterments are capitalized as additions to property and equipment. Property and equipment not yet placed into service is capitalized as construction in progress and is depreciated once placed into service. Leasehold improvements are depreciated over the **requisite service period, which is generally** lesser of their useful lives or the **vesting period** term of the **respective award**, lease. Depreciation, including depreciation for assets recorded under finance leases, is calculated over the estimated useful lives of the assets using the straight-line method.

Impairment of Long-lived Assets

The Company reviews long-lived assets when events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Recoverability is measured by comparing the carrying value of the asset to the future undiscounted cash flows from the use and eventual disposition of the asset. If an asset is considered to be impaired, the impairment loss to be recognized is measured as the amount by which the carrying value of the asset exceeds its fair value.

Leases

Under ASC Topic 842, *Leases* ("ASC 842"), the Company determines whether an arrangement is or contains a lease at inception. For **stock-based awards granted** leases with a term of 12 months or less, the Company does not recognize a right-of-use asset or lease liability. The Company's operating leases are recognized on its consolidated balance sheets as noncurrent assets, current liabilities and noncurrent liabilities. The Company does not have any finance leases.

Right-of-use assets represent the Company's right to **non-employees, compensation** use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. As the Company's leases typically do not provide an implicit rate, the Company uses an estimate of its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments. Lease expense is recognized on a straight-line basis over the **period during which services** lease term. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew or options to terminate a lease are **rendered by** not included in the Company's assessment unless there is reasonable certainty that the Company will exercise such **non-employees until completed** options, respectively.

The Company has elected to account for the lease and non-lease components together for existing classes of underlying assets.

Preferred Stock

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We The Company applies the guidance of ASC Topic 480, *Distinguishing Liabilities from Equity* ("ASC 480"), when determining the classification and measurement of preferred stock. Preferred stock subject to mandatory redemption (if any) are classified as liability instruments and are measured at fair value. The Company classifies contingently redeemable preferred stock (if any), which includes preferred stock that features redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control, as temporary equity. At all other times, the Company classifies its preferred stock in stockholders' equity (deficit).

Prior to the merger, Legacy Korro classified its convertible preferred stock as temporary equity due to terms that allowed for redemption of the shares upon the occurrence of a contingent event that was not solely within the Legacy Korro's control. Legacy Korro did not accrete the carrying values of the preferred stock to the redemption value since the contingent event was not considered probable.

Research and Development Expenses

Expenditures relating to research and development are expensed as incurred. Research and development expenses include external expenses incurred under arrangements with third parties, academic and non-profit institutions and consultants; salaries and personnel-related costs, including non-cash stock-based compensation expense; license fees to acquire in-process technology and other expenses, which include direct and allocated expenses for laboratory, facilities and other costs. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed when the goods have been received rather than when the payment is made.

As part of the process of preparing the consolidated financial statements, the Company is required to estimate its accrued research and development expenses as of balance sheet date. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in the period. This process involves reviewing open contracts and purchase orders, communicating with internal personnel to identify services that have been performed on the Company's behalf and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of the actual cost. The Company periodically confirms the accuracy of its estimates with its service providers and makes adjustments if necessary. The majority of the Company's service providers invoice monthly in arrears for services performed or when contractual milestones are met. The financial terms of agreements with the service providers are subject to negotiation, vary from contract-to-contract and may result in uneven payment flows. In circumstances where amounts have been paid in excess of costs incurred, the Company records a prepaid expense.

Intellectual Property Expenses

The Company expenses legal costs related to patent applications as they are incurred. Such costs are classified as general and administrative expenses within the consolidated statements of operations and comprehensive loss.

Stock-based Compensation

The Company accounts for stock-based payments in accordance with ASC Topic 718, *Compensation—Stock Compensation* ("ASC 718"). This guidance requires all stock-based payments, including grants of stock options and restricted common stock, to be recognized as expense in the consolidated statements of operations and comprehensive loss based on their grant date fair values. For stock options granted to employees, non-employees and members of the Company's Board of Directors for their services on the Board of Directors, the Company estimates the grant date fair value of each stock option using the Black-Scholes option pricing model. For restricted common stock granted to employees and non-employees, the Company estimates the grant date fair value of each award using the intrinsic value, which is based on the value of the underlying common stock less any purchase price. For stock-based payments subject to service-based vesting conditions, the Company recognizes stock-based compensation expense equal to the grant date fair value of stock-based payment on a straight-line basis over the requisite service period.

Prior to the merger, due to the absence of an active market for Legacy Korro's common stock, Legacy Korro and its Board were required to determine the fair value of Legacy Korro's common stock at the time of each grant of a stock-based award. Legacy Korro estimated the grant date fair value of its common stock using an appropriate valuation methodology, in accordance with the framework of the American Institute of Certified Public Accountants' Technical Practice Aid, *Valuation of Privately Held Company Equity Securities Issued as Compensation*. Historically, the Company has utilized a market approach to determine its total equity value and the option method ("OPM") to allocate this equity value among various classes of securities. The OPM treats common stock and convertible preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under the OPM, the common stock has value only if the funds available for distribution to stockholders exceeds the value of the

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convertible preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock.

Each valuation methodology includes estimates and assumptions that required the Legacy Korro's judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, guideline public company information, the prices at which Legacy Korro sold convertible preferred stock to third parties in arms' length transactions, the rights and preferences of securities senior to Legacy Korro's common stock at the time and the likelihood of achieving a liquidity event such as an initial public offering or sale. Significant changes to the assumptions used in the valuations could result in different fair values of stock options and restricted stock at each valuation date, as applicable.

In addition to the grant date fair value of the Company's common stock, the Black-Scholes option pricing model requires the input of certain subjective assumptions, including (i) the calculation of expected term of the stock-based payment, (ii) the risk-free interest rate, (iii) the expected stock price volatility and (iv) the expected dividend yield. The Company uses the simplified method as proscribed by SEC Staff Accounting Bulletin No. 107 to calculate the expected term for stock options granted to employees as the Company does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The Company determines the risk-free interest rate based on a treasury instrument whose term is consistent with the expected term of the stock options. Due to the lack of Company-specific historical and implied volatility data, the Company bases its estimates of expected volatility on the historical volatility of a group of publicly-traded companies with similar characteristics to itself, including stage of product development and therapeutic focus within the life sciences industry. The expected volatility has been determined using a weighted-average of the historical volatility measures of this group of companies. The Company expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. Historical volatility is calculated over a period that approximates the time

commensurate with the expected term of **our** the stock-based payment. The Company uses an assumed dividend yield of zero as the Company has never paid dividend on its common stock, **options**, nor does it expect to pay dividends on its common stock in the foreseeable future.

The Company accounts for forfeitures of all stock-based payments when such forfeitures occur.

Income Taxes

Income taxes are recorded in accordance with ASC Topic 740, *Income Taxes*, which provides for deferred taxes using an asset and **our** liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted rates in effect for the year in which the differences are expected to reverse. A valuation allowance against deferred tax assets is recorded if, based on the weight of the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions using a more-likely-than-not threshold for recognizing and resolving uncertain tax positions. The evaluation of uncertain tax positions is based on factors, including, but not limited to, changes in the law, the measurement of tax positions taken or expected to be taken in tax returns, the effect of settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position.

Interest and penalty charges, if any, related to income taxes would be classified as a component of the "Provision for income taxes" in the consolidated statements of operations and comprehensive loss.

Net Loss per Share

Net loss per share attributable to common stockholders is calculated using the two-class method, which is an earnings allocation formula that determines net loss per share for the holders of the Company's common shares and participating securities. The Company's Preferred Stock contains participation rights in any dividend **yield**. **Although we** paid by the Company and is deemed to be a participating security. Net income attributable to common stockholders and participating preferred shares are allocated to each share as if all of the earnings for the period had been distributed. The participating securities do not **expect our estimates** include a contractual obligation to **be** materially different from amounts actually incurred, **our option pricing model may cause us** share in losses of the Company and are not included in the calculation of net loss per share in the periods in which a net loss is recorded. Net loss attributable to **report amounts that are too high** common stockholders is equal to the net loss for the period.

Diluted net loss per share is computed using the more dilutive of (a) the two-class method or **too low** (b) the treasury stock method and if-converted method. The Company allocates earnings first to preferred stockholders based on dividend rights and then to common and preferred stockholders based on ownership interests. The weighted average number of common shares included in **any particular period**. **To date, we have not made any material adjustments** the computation of diluted net loss gives effect to **our prior estimates of stock-based compensation expense**, all potentially dilutive common equivalent shares, including outstanding stock.

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Recent accounting pronouncements options and Preferred Stock. Common stock equivalent shares are excluded from the computation of diluted net loss per share if the effect is antidilutive. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is generally the same as basic net loss per share attributable to common stockholders since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Concentration of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially expose the Company to concentrations of credit risk primarily consist of cash, cash equivalents and investments. Cash balances are deposited with federally-insured financial institutions in the United States and may, at times, exceed federally-insured limits. The Company maintains its cash, cash equivalents and investments with high-quality financial institutions and, consequently, the Company believes that such funds are subject to minimal credit risk. The Company's cash equivalents are comprised of money market funds that are invested in U.S. Treasury and government agency obligations. The Company's investments are comprised of commercial paper and government securities. Credit risk in these securities is reduced as a result of the Company's investment policy to limit the amount invested in any single issuer and to only invest in securities of a high credit quality.

A description The Company relies, and expects to continue to rely, on a small number of **recent accounting pronouncements that may potentially impact our financial position, results of operations**, vendors to manufacture supplies and to process its product candidates for its development programs. These programs could be adversely affected by a significant interruption in the manufacturing process or **cash flows is disclosed below**: supply chain.

82 The Company has no significant off-balance sheet risk such as foreign exchange contracts, option contracts or other foreign hedging arrangements.

Emerging growth company status

The Company qualifies as an "emerging growth company" ("EGC"), as defined in the Jumpstart Our Business Startups Act ("JOBS Act"), and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not EGCs. The Company may take advantage of these exemptions until it is no longer an EGC under Section 107 of the JOBS Act, which provides that an EGC can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. The Company has elected to avail itself of the extended transition period and, therefore, while the Company is an EGC it will not be subject to new or revised accounting standards the same time that they become applicable to other public companies that are not EGCs, unless it chooses to early adopt a new or revised accounting standard. As a result of this election, the consolidated financial statements may not be comparable to companies that comply with public company FASB standards' effective dates.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses* (Topic 326): Measurement of Credit Losses on Financial Instruments. The FASB Instruments, which has been subsequently issued amendments to amended by ASU 2016-13, which have the same effective date 2018-19, ASU 2019-04, ASU 2019-05, ASU 2019-10, ASU 2019-11, ASU 2020-03, and transition date. These standards require ASU 2022-02 ("ASU 2016-13"). This standard requires that credit losses be reported recorded using an expected losses model rather than the incurred losses model that was previously used and establishes additional credit risk disclosures related to credit risks. For available-for-sale debt securities associated with unrealized losses, financial assets. The amendments in this standard now requires allowances shown applied on a modified retrospective basis to all periods presented. The Company adopted ASU 2016-13 on January 1, 2023 using the modified retrospective approach. Adoption of this standard did not have a material effect on the Company's financial position, results of operations or disclosures.

Recent Accounting Pronouncements—Yet to be recorded instead of reducing Adopted

Other accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and requires the reversal of previously recognized credit losses if fair value increases. We adopted this standard on January 1, 2023 and did not have a material impact on the Company's consolidated financial statements upon adoption.

In November 2023, the FASB issued Accounting Standards Update ("ASU") 2023-07, *Segment Reporting (Topic 280), Improvements to Reportable Segment Disclosures*, which is intended to provide enhanced segment disclosures. The standard will require disclosures about significant segment expenses and other segment items and identifying the Chief Operating Decision Maker and how they use the reported segment profitability measures to assess segment performance and allocate resources. These enhanced disclosures are no other recent accounting pronouncements that we believe required for all public entities on an interim and annual basis, if they have only a single reportable segment. The standard is effective for years beginning after December 15, 2023, and interim periods within annual periods beginning after December 15, 2024. Early adoption is permitted. The Company is evaluating this standard to determine if adoption will have a material impact on our consolidated financial statements.

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3. Reverse Merger

As described in Note 1, Legacy Korro merged with Frequency on November 3, 2023. The merger was accounted for as a reverse recapitalization with Legacy Korro as the accounting acquirer. The primary pre-combination assets of Frequency were cash and cash equivalents. Under reverse recapitalization accounting, the assets and liabilities of Frequency were recorded at their fair value which approximated book value due to the short-term nature of the accounts. No goodwill or intangible assets were recognized. Consequently, the consolidated financial statements of the Company reflect the operations of Legacy Korro for accounting purposes, together with a deemed issuance of shares equivalent to the shares held by the former stockholders of Frequency, the legal acquirer, and a recapitalization of the equity of Legacy Korro, the accounting acquirer.

As part of the reverse recapitalization, the Company acquired \$36.6 million of cash and cash equivalents. The Company also obtained prepaids and other assets of \$1.5 million and assumed accounts payable and accrued expenses of \$5.4 million. Frequency's development programs had ceased prior to the merger and were deemed to have minimal value at the transaction date.

In addition, the Company recognized \$0.3 million in share-based compensation expense as a result of the acceleration of vesting of stock options, performance stock and restricted stock units at the time of merger. This amount was recorded in general and administrative expense in the accompanying consolidated statements of operations and comprehensive loss for the year ended December 31, 2023. The company recognized \$2.5 million in personnel cost related to the severance payment to Frequency employees and this amount was recorded in general and administrative expense in the accompanying consolidated statements of operations and comprehensive loss.

loss for the year ended December 31, 2023. The Company also incurred transaction costs of \$12.2 million and this amount is recorded in additional paid-in capital in the accompanying consolidated statements of convertible preferred stock and stockholders' equity (deficit) for the year ended December 31, 2023.

4. Fair Value Measurements

The Company measures the fair value of money market funds based on quoted prices in active markets for identical securities. Investments also include commercial and government securities that are valued either based on recent trades of securities in inactive markets or based on quoted market prices of similar instruments and significant inputs derived from or corroborated by observable market data. The carrying amounts reflected in the consolidated balance sheets for cash, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values, due to their short-term nature.

Assets measured at fair value on a recurring basis as of December 31, 2023 were as follows (in thousands):

		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	Total			
Money market funds, included in cash and cash equivalents	\$ 158,706	\$ 158,706	\$ —	\$ —
MS APA asset	\$ 1,448	\$ —	\$ —	\$ 1
Total	\$ 160,154	\$ 158,706	\$ —	\$ 1

Item 7A. Quantitative Assets measured at fair value on a recurring basis as of December 31, 2022 were as follows (in thousands):

		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	Total			
Money market funds, included in cash and cash equivalents	\$ 14,904	\$ 14,904	\$ —	\$ —
Short-term investments:				
Commercial paper	\$ 14,935	\$ —	\$ 14,935	\$ —
Government securities	\$ 3,980	\$ —	\$ 3,980	\$ —
Total	\$ 33,819	\$ 14,904	\$ 18,915	\$ —

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As noted previously in Note 1, at the effective time of the Transaction, the Company entered into the CVR Agreement providing for the payment of certain contingent payments equal to the net amount of proceeds actually received by the Company or its subsidiaries after the end of each fiscal quarter following the first anniversary closing of the Transaction related to the disposition of assets related to the Company's former multiple sclerosis programs, with the time periods and **Qualitative Disclosures About Market Risk**, subject to deductions as provided therein. The Company concluded that the CVR is a derivative liability and is accounted for at fair value, which was \$1.4 million as of December 31, 2023 of which \$0.4 million is included in accrued expenses and other current liabilities and the remaining \$1.0 million in other non-current liabilities in the consolidated balance sheet. Concurrently, the Company entered into the MS APA with Progentos, whereby Progentos acquired the rights, title and interest in certain assets related to the Company's MS program. The MS APA included initial consideration of \$0.5 million in proceeds that were settled through net cash at the net closing and will be entitled to future milestone payments of up to \$17.5 million as well as a \$0.7 million payment in the event of Progentos closing of an equity financing above a specified amount. The Company concluded that the MS APA is a derivative asset and is accounted for at fair value, which was \$1.4 million as of December 31, 2023 of which \$0.4 million is included in prepaid and other current assets and the remaining \$1.0 million in other long-term assets in the consolidated balance sheet.

The fair value of the CVR liability and the MS APA are based on significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy. In determining the fair value of the CVR liability and the MS APA asset, the Company used the income approach, primarily discounted cash flow models. The discounted cash flow models require the use of significant judgment, estimates and assumptions, including the probability of technical and regulatory success, and discount rates. For the year ended December 31, 2023, the aggregate change in fair value of the CVR liability and MS APA asset was \$0.08 million.

There were no liabilities measured at fair value on a recurring basis as of December 31, 2022.

There were no changes in valuation techniques, nor were there any transfers among the fair value hierarchy levels during the years ended December 31, 2023 or 2022.

5. Investments

The Company did not have investments as of December 31, 2023.

Short-term investments as of December 31, 2022 were comprised as follows (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Commercial paper	\$ 14,935	\$ —	\$ —	\$ 14,935
Government securities	3,985	—	(5)	3,980
Total	\$ 18,920	\$ —	\$ (5)	\$ 18,915

We are exposed

As of December 31, 2022, the aggregate fair value of securities that were in an unrealized loss position for less than twelve months was \$4.0 million. As of December 31, 2022, the Company held no securities that were in an unrealized loss position for more than twelve months. As of December 31, 2022, the Company did not intend to sell, and would not be more likely than not required to sell, the securities in an unrealized loss position before recovery of their amortized cost bases. Furthermore, the Company determined that there was no material change in the ordinary course credit risk of our business. These risks primarily include interest rate sensitivities. Our interest-earning assets consist of these securities. As a result, the Company determined it did not hold any securities with any other-than-temporary impairment as of December 31, 2022.

6. Restricted Cash

As of December 31, 2023, the Company maintained current restricted cash of \$3.6 million and non-current restricted cash of \$3.4 million. As of December 31, 2022, the Company maintained current restricted cash of \$0.6 million and non-current restricted cash of \$4.5 million. All restricted cash amounts are comprised solely of letters of credit required pursuant to the Company's facility leases.

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The following table provides a reconciliation of cash, cash equivalents and marketable securities, restricted cash as of December 31, 2023 and 2022 that sums to the same amounts shown in the consolidated statements of cash flows (in thousands):

	December 31,	
	2023	2022
Cash and cash equivalents	\$ 166,150	\$ 36,300
Restricted cash	6,969	5,100
Cash, cash equivalents and restricted cash	\$ 173,119	\$ 41,400

7. Property and Equipment, Net

Property and equipment, net, as of December 31, 2023 and 2022 was comprised as follows (in thousands):

	Estimated Useful Life (in Years)	December 31,	
		2023	2022
Laboratory equipment	5	\$ 11,187	\$ 8,400
Furniture and office equipment	4	481	400
Computer equipment	3	241	200
Leasehold improvements	Shorter of useful life or remaining lease term	3,356	2,900
Construction in progress		8,242	2,000
Total property and equipment, gross		23,507	14,100
Less: accumulated depreciation		(7,842)	(4,200)
Total property and equipment, net		\$ 15,665	\$ 9,900

As of December 31, 2023 and 2022, the Company had construction in progress of \$8.2 million and \$2.0 million, predominately related to laboratory equipment received but not yet installed and capitalizable costs related to the Company's future corporate headquarters.

Depreciation expense for the years ended December 31, 2023 and 2022 was \$3.6 million and \$2.5 million, respectively.

8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities as of December 31, 2023 and 2022 were comprised as follows (in thousands):

	December 31,	
	2023	2022
Employee compensation and benefits	\$ 7,896	\$ 2,612
External research and development services	1,255	2,000
Other operating expenses	447	2,000
CVR liability, current	395	—
Professional fees	219	—
Total accrued expenses and other current liabilities	\$ 10,212	\$ 3,112

9. Common Stock

At the closing of the merger, the shares of Legacy Korro common stock were converted into shares of the Company's common stock based on the exchange ratio determined in the Merger Agreement.

As of December 31, 2023, the Company was authorized to issue 200,000,000 shares of common stock, \$0.001 per value per share. Prior to the merger, the holders of Legacy Korro's common stock were subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock set forth in Note 10. Holders of common stock are entitled to one vote per share. In addition, holders of common stock are entitled to receive dividends, if and when declared by the Company's Board of Directors. As of December 31, 2023, no dividends had been declared.

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As of December 31, 2023 and 2022, the Company had reserved for future issuance the following number of shares of common stock:

	December 31,	
	2023	2022
Conversion of outstanding Legacy Korro Series Seed Preferred Stock	—	684,739
Conversion of outstanding Legacy Korro Series A Preferred Stock	—	2,029,666
Conversion of outstanding Legacy Korro Series B-1 Preferred Stock	—	1,104,178
Conversion of outstanding Legacy Korro Series B-2 Preferred Stock	—	223,417
Future issuances of Legacy Korro Series B-2 Preferred Stock	—	813,239
Vesting of restricted common stock	—	2,902
Exercises of outstanding stock options	1,323,151	461,128
Exercise of outstanding warrant	8,049	8,049
Future issuances under 2019 Stock Incentive Plan	—	159,890
Future issuances under 2023 Stock Incentive Plan	255,694	—
Future issuances under 2023 ESPP Plan	88,502	—
Total reserved for future issuance	1,675,396	5,487,208

10. Preferred Stock

As of December 31, 2023, the Company was authorized to issue up to 10,000,000 shares of preferred stock at a par value of \$0.001 with no preferred stock shares issued or outstanding.

Pursuant to the terms of the Merger Agreement, immediately prior to closing of the Merger, each share of Legacy Korro's Preferred Stock issued and outstanding immediately prior to the Closing of the Merger was converted into shares of the Legacy Korro's common stock, and then exchanged in the Merger for shares of the Company's common stock using an exchange ratio of 0.049688. The conversion was approved by greater than 66% of the then-outstanding shares of Preferred Stock voting as a single class on an as-converted to common stock basis.

As of December 31, 2022, Legacy Korro was authorized to issue up to 10,000,000 shares of preferred stock at a par value of \$0.001 with no preferred stock shares issued or outstanding. As of December 31, 2022, Legacy Korro Preferred Stock authorized, issued and outstanding consisted of the following (in thousands, except share

amounts):

	December 31, 2022				
	Preferred				Common
	Preferred	Stock Issued	Carrying	Liquidation	Stock
	Stock	and			Issuable Upon
	Authorized	Outstanding	Value	Value	Conversion
Legacy Korro Series Seed Preferred Stock	684,739	684,739	15,924	\$ 16,115	684,739
Legacy Korro Series A Preferred Stock	2,029,666	2,029,666	77,736	91,500	2,029,666
Legacy Korro Series B-1 Preferred Stock	1,104,178	1,104,178	57,703	58,000	1,104,178
Legacy Korro Series B-2 Preferred Stock	1,036,656	223,417	12,500	12,500	223,417
Total	4,855,239	4,042,000	\$ 163,863	\$ 178,115	4,042,000

Rights, Preferences and Privileges of Legacy Korro Preferred Stock

The Legacy Korro Preferred Stock as of December 31, 2022 had the following rights and preferences. In the discussion below, the Legacy Korro Series Seed Preferred Stock and the Legacy Korro Series A Preferred Stock, the Legacy Korro Series B-1 Preferred Stock and the Legacy Korro Series B-2 Preferred Stock are collectively referred to as the "Legacy Korro Preferred Stock" unless specifically noted.

Conversion

Each share of Legacy Korro Preferred Stock were convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of common stock as is determined by dividing the original issuance price of the conversion price in effect at the time of conversion. The original conversion price of the Legacy Korro Series Seed 1 Preferred Stock and Legacy Korro Series Seed 2 Preferred Stock was \$20.13, the original conversion price of the Legacy Korro Series Seed 3 Preferred Stock was \$26.16, the original conversion price of the Legacy Korro Series A Preferred Stock was \$45.08, the original conversion price of the Legacy Korro Series B-1 Preferred Stock was \$52.53 and the original conversion price of the Legacy Korro Series B-2 Preferred Stock was \$55.95. Shares of Legacy Korro preferred stock are subject to adjustments to reflect the issuance of common stock.

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options, warrants, or other rights to subscribe for or to purchase common stock for a consideration per share, less than the conversion price then in effect and subsequent stock dividends, stock splits, combinations, or recapitalizations.

The Legacy Korro Preferred Stock was subject to mandatory conversion upon the closing of a sale of common stock to the public at a price of at least \$111.90 per share (subject to appropriate adjustment in the event of a stock dividend, stock split, combination or other similar recapitalization) in a firm-commitment underwritten public offering resulting in at least \$75.0 million of gross proceeds to Legacy Korro. The Legacy Korro Preferred Stock was also subject to mandatory conversion upon the vote or written consent of the holders of at least 66% of the then-outstanding shares of Legacy Korro Preferred Stock, voting as a single class on an as-converted to common stock basis.

Dividends

The holders of Legacy Korro Preferred Stock, in preference to common stockholders, were entitled to receive, when, as and if declared by the Company's Board of Directors, dividends at a rate of 8% annually. Dividends on Legacy Korro Preferred Stock were non-cumulative and were payable only when and if declared by Legacy Korro's Board of Directors. The holders of Legacy Korro Preferred Stock were entitled to participate in dividends on common stock on an as-converted basis when and if declared by Legacy Korro's Board of Directors. Since Legacy Korro's inception, no dividends have been declared.

Liquidation Preference

In the event of any voluntary or involuntary liquidation, dissolution, winding up or deemed liquidation event of Legacy Korro, the holders of shares of Legacy Korro Preferred Stock then outstanding were entitled to be paid out of the assets of Legacy Korro available for distribution to its stockholders before any payment shall be made to the holders of common stock, an amount equal to the original issue price per share plus any dividends declared but unpaid thereon. For clarity, the original issue price of the Legacy Korro Series Seed 1 Preferred Stock and Legacy Korro Series Seed 2 Preferred Stock was \$20.13 per share, the original issue price of the Legacy Korro Series Seed 3 Preferred Stock was \$26.16 per share, the original issue price of the Legacy Korro Series A Preferred Stock was \$45.08 per share, the original issue price of the Legacy Korro Series B-1 Preferred Stock was \$52.53 per share and the original issue price of the Legacy Korro Series B-2 Preferred Stock was \$55.95 per share.

If upon any voluntary or involuntary liquidation, dissolution, winding up or deemed liquidation event of Legacy Korro, the assets of Legacy Korro available for distribution were insufficient to pay the holders of Legacy Korro Preferred Stock the full amount to which they were entitled, the holders of shares of Legacy Korro Preferred Stock

share ratably in any distribution of the assets available for distribution in proportion to the respective amounts that would otherwise be payable in respect of the shares by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

Redemption

The Legacy Korro Preferred Stock was contingently redeemable upon the occurrence of a deemed liquidation event, which included a merger or a sale of substantially all the assets of Legacy Korro. As of December 31, 2022, a deemed liquidation event was not considered to be probable.

Voting Rights

The holders of Legacy Korro Preferred Stock were entitled to vote based on the number of common shares that their preferred shares converted into on an as-converted basis at the time of such vote. Except in specific circumstances, holders of Legacy Korro Preferred Stock shall vote as a single class with the common stockholders.

The holders of record of the shares of the Legacy Korro Series Seed Preferred Stock, voting exclusively and as a separate class on an as-converted to common stock basis, were entitled to elect two members to Legacy Korro's Board of Directors. The holders of record of the shares of the Legacy Korro Series A Preferred Stock, voting exclusively and as a separate class on an as-converted to common stock basis, were entitled to elect two members to the Legacy Korro's Board of Directors. The holders of record of the shares of the Legacy Korro Series B Preferred Stock, voting exclusively and as a separate class on an as-converted to common stock basis, were entitled to elect two members to the Legacy Korro's Board of Directors.

11. Stock-based Compensation

2023 Stock Option and Incentive Plan

In November 2023, the Company's board of directors adopted the Company's 2023 Stock Option and Incentive Plan (the "2023 Plan"). The 2023 Plan was approved by the Company's stockholders in November 2023 and became effective in November 2023.

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in connection with completion of the Merger. The 2023 Plan initially reserved 885,028 shares for the issuance of stock awards. In addition, the number of shares of common stock available for issuance under the 2023 Plan will be automatically increased on the first day of each calendar year during the ten-year term of the 2023 Plan, beginning with January 1, 2024 and ending with January 1, 2033, by the amount equal to 5% of the outstanding number of shares of the Company's common stock on December 31 of the preceding calendar year or such lesser amount as determined by the Company's board of directors. Awards granted under the 2023 Plan expire no later than ten years from the date of grant. For stock options, the option price shall generally not be less than 100% of the fair market value on the day of grant. As of December 31, 2023, there were in aggregate 889,922 shares of common stock reserved for issuance and 255,694 shares available to grant under the 2023 Plan.

2019 Stock Incentive Plan

In January 2019, the Legacy Korro's Board of Directors adopted the 2019 Stock Incentive Plan (as amended from time to time, the "Legacy Korro Plan"). The Legacy Korro Plan provides for the grant of stock options, stock awards and restricted stock units to employees, members of the Company's Board of Directors and non-employee consultants and advisors. The Legacy Korro Plan initially provided for the issuance of up to 110,285 shares of common stock. The Legacy Korro Plan was subsequently amended in May 2019, June 2020, October 2020, April 2021, November 2021 and March 2023 to modify the number of shares of common stock issuable under the Legacy Korro Plan. Subsequent to the March 2023 amendment to the Legacy Korro Plan, Legacy Korro could issue up to 747,752 shares of common stock under the Legacy Korro Plan.

In connection with the merger, each option to purchase shares of Legacy Korro common stock that was outstanding and unexercised under the Legacy Korro Plan immediately prior to the Effective Time, whether or not vested, was converted into an option to purchase shares of the Company's common stock and became eligible to be registered on Form S-8. The Company assumed each outstanding option to purchase shares of Legacy Korro common stock in accordance with the terms (as in effect on the date of the Merger Agreement) of the Legacy Korro Plan and the terms of the stock option agreement by which such option to purchase shares of Legacy Korro common stock is evidenced. The number of shares under the Legacy Korro Plan subject to outstanding awards as of the effective date of the 2023 Plan that are **denominated** subsequently canceled, forfeited or repurchased by the Company will be added to the shares reserved under the 2023 Plan.

The number of shares of common stock reserved for issuance pursuant to outstanding awards under the Legacy Korro Plan as of December 31, 2023 and 2022 was 600,977 shares and 683,156 shares, respectively. The number of shares available for grant under the Legacy Korro Plan was 0 and 159,890 at December 31, 2023 and 2022, respectively. Upon completion of the Merger and effectiveness of the 2023 Plan, the Company ceased granting awards under the Legacy Korro Plan.

2014 Stock Incentive Plan

On November 13, 2014, Frequency adopted the 2014 Stock Incentive Plan (as amended from time to time, the "2014 Plan"). All of Frequency's employees, officers, directors, and consultants were eligible to be granted options to purchase common shares, restricted stock units and restricted stock under the terms of the 2014 Plan. Frequency reserved an aggregate of 424,853 shares of common stock for issuance under the 2014 Plan. The number of shares under the 2014 Plan subject to outstanding awards as of December 31, 2023 and 2022 was 0 and 0, respectively.

awards as of the effective date of the 2023 Plan that are subsequently canceled, forfeited or repurchased by the Company will be added to the shares reserved under 2023 Plan. As of December 31, 2023, there were no shares of common stock available for future grants under the 2014 Plan and there were 36,455 shares subject to outstanding option awards under the 2014 Plan.

2019 Incentive Award Plan

On September 17, 2019, Frequency’s board of directors and on September 19, 2019, its stockholders approved and adopted the 2019 Incentive Award Plan (the “201 Plan”). Under the 2019 Plan, Frequency may grant stock options, stock appreciation rights, restricted stock, restricted stock units, and other stock and cash-based aw to individuals who are then employees, officers, directors or consultants of the Company, and employees and consultants of the Company’s subsidiaries. A total of 15 shares of common stock were approved to be initially reserved for issuance under the 2019 plan. The number of shares under the 2019 Plan subject to outstanding a as of the effective date of the 2023 Plan that are subsequently canceled, forfeited or repurchased by the Company will be added to the shares reserved under the 202 Plan. Upon completion of the Merger and effectiveness of the 2023 Plan, the Company ceased granting awards under the 2019 Plan. Accordingly, as of December 31 2023, there were no shares of common stock available for future grants under the 2019 Plan and there were 51,491 shares subject to outstanding option awards unde 2019 Plan.

All stock option grants are non-statutory stock options except option grants to employees (including officers and directors) intended to qualify as incentive stock option under the IRC. Incentive stock options may not be granted at less than the fair

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market value of the Company’s common stock on the date of grant. Nonqualified stock options may be granted at an exercise price established by the Board of Direct its sole discretion (which has not been less than fair market value on the date of grant) and the vesting periods may vary. Vesting periods are generally four years and determined by the Board of Directors. Stock options generally become exercisable as they vest. Options granted under the Legacy Korro Plan, 2014 Plan and the 201 expire no more than ten years from the date of grant.

Stock-based Compensation Expense

Total stock-based compensation expense recognized in U.S. dollars. We the consolidated statements of operations and comprehensive loss for the years ended Dece 31, 2023 and 2022 was as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Research and development	\$ 759	\$
General and administrative	1,622	
Total stock-based compensation expense	\$ 2,381	\$ 1

Restricted Common Stock Activity

Prior to the adoption of the 2019 Plan, Legacy Korro issued shares of restricted common stock to its founders as well as to certain employees. The restrictions on the common stock generally lapse over two to four years. In the event that a recipient ceases to provide service to Legacy Korro, Legacy Korro has the right to repurchase unvested shares of restricted common stock at their original purchase price. As a result of this repurchase right, Legacy Korro recorded the issuance of such restricte common stock as a liability in the consolidated balance sheets. Amounts are reclassified to common stock at par and additional paid-in capital as the restricted comm stock vests and restrictions lapse.

The following table summarizes Legacy Korro restricted common stock activity during the year ended December 31, 2023:

	Shares	Weighted-Average Grant Date Fair Value per Share
Unvested as of December 31, 2022	2,902	\$
Granted	—	\$
Vested	2,902	\$
Repurchased	—	\$
Unvested as of December 31, 2023	—	\$

The aggregate fair value of Legacy Korro restricted common stock that vested during the years ended December 31, 2023 and 2022, based upon the fair value of the underlying restricted common stock on the day of vesting, was \$0.1 million and \$0.5 million, respectively.

Stock Option Activity

The fair value of stock options granted during the years ended December 31, 2023 and 2022 was calculated on the date of grant using the following weighted-average assumptions:

	Year Ended December 31,	
	2023	2022
Risk-free interest rate	4.3 %	
Expected dividend yield	—%	
Expected term (in years)	6.0	
Expected volatility	72.8 %	

Using the Black-Scholes option pricing model, the weighted-average grant date fair value of stock options granted during the years ended December 31, 2023 and 2022 was \$23.49 and \$14.95 per share, respectively.

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The following table summarizes changes in stock option activity during the year ended December 31, 2023 (in thousands, except per share amounts):

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2022	461,100	\$ 14.95	8.0	\$ 2.0
Assumed in reverse recapitalization	93,153	\$ 121.91		
Granted	835,839	\$ 17.33		
Exercised	(39,395)	\$ 16.41		
Forfeited	(20,091)	\$ 20.07		
Cancelled	(7,455)	\$ 18.85		
Outstanding as of December 31, 2023	1,323,151	\$ 23.49	8.4	\$ 36.0
Exercisable at December 31, 2023	368,036	\$ 34.60	6.7	\$ 8.0

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock as of the end of the period. The aggregate intrinsic value of those stock options that had cash, cash equivalents exercise prices lower than the fair value of the common stock as of the end of the period. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2023 and marketable securities 2022 was \$0.3 million and \$0.1 million, respectively.

As of \$83.1 million December 31, 2023, there was unrecognized stock-based compensation expense related to unvested stock options of \$10.1 million, which the Company expects to recognize over a weighted-average period of approximately 3.1 years.

12. Income Taxes

The provision for income taxes for the years ended December 31, 2023 and 2022 was comprised as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Current taxes:		
Federal	\$ —	\$ —
State	27	—
Total current taxes	27	—
Deferred taxes:		
Federal	—	—
State	—	—
Total deferred taxes	—	—
Total provision for income taxes	\$ 27	\$ —

A reconciliation of the federal statutory income tax rate to the Company's effective tax rate is as follows:

	December 31,	
	2023	2022
Income tax computed at federal statutory rate	21.0%	21.0%
State taxes, net of federal benefit	7.1%	7.1%
Tax credit carryforwards	3.6%	3.6%
Permanent items	(1.0)%	(1.0)%
Change in valuation allowance	(30.8)%	(30.8)%
Other	0.1%	0.1%
Effective tax rate	—%	—%

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The principal components of the Company's deferred tax assets and liabilities as of December 31, 2023 and 2022 were comprised as follows (in thousands):

	December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	\$ 80,385	\$ 19,500
Tax credit carryforwards	22,474	5,400
Capitalized research and development	34,395	10,200
Stock-based compensation	4,494	3,000
Amortization	1,138	1,000
Operating lease liability	9,052	8,000
Accrued expenses and other temporary differences	1,543	7,000
Total deferred tax assets	153,481	37,200
Less: valuation allowance	(145,766)	(36,000)
Net deferred tax assets	7,715	1,200
Deferred tax liabilities:		
Operating right-of-use asset	(7,401)	(5,000)
Depreciation	(314)	(5,000)
Total deferred tax liabilities	(7,715)	(1,200)
Net deferred taxes	\$ —	\$ —

As of December 31, 2023, the Company had federal and state net operating loss ("NOL") carryforwards of \$302.5 million and \$266.3 million, respectively. Under current law, the Company's federal NOLs generated in taxable years ending after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80% of the Company's taxable income annually for tax years beginning after December 31, 2018. Federal NOLs generated in taxable years ending on or before December 31, 2017, however, have a 20-year carryforward period, but are not subject to the 80% limitation. The Company has federal NOLs of our total \$22.4 million that are subject to expiration between 2036 and 2037 and has \$280.1 million of federal NOLs that do not expire.

State NOLs expire at various dates from 2035 through 2043. As of December 31, 2023, the Company had federal research and development tax credit carryforwards of \$15.6 million that expire at various dates from 2036 through 2043. In addition, as of December 31, 2023, the Company had state research and development tax credit carryforwards of \$8.7 million that expire at various dates from 2032 through 2038.

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which primarily pertain to NOL carryforwards, tax credit carryforwards and capitalized research and development. The Company has determined that it is more likely than not that it will not realize the benefits of its deferred tax assets, and as a result, a valuation allowance of \$145.8 million has been established at December 31, 2023. Interest The increase in the valuation allowance of \$109.7 million during the year ended December 31, 2023 was primarily due to the additional operating loss generated by the Company and the combination of deferred tax assets as a result of the Merger.

NOL and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50% as defined under Sections 382 and 384 in the IRC. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income earned or tax liabilities. The amount of the annual limitation is determined based on these assets was \$1.3 million the Company's value immediately prior to the ownership change. As a result of ownership changes in 2023, the Company's value immediately prior to the ownership change was \$1.3 million.

Company from its inception through December 31, 2023, the Company's NOL and tax credit carryforwards allocable to the periods preceding each such ownership change could be subject to limitations under IRC Section 382, however the Company has not yet completed an IRC Section 382 study.

The Company had no unrecognized tax benefits as of either December 31, 2023 or 2022. The Company has not conducted a study of its research and development credit carryforwards generated during any year. This study, once completed, may result in an adjustment to the Company's research and development credit carryforwards.

However, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and development credit carryforwards, and if an adjustment is required, this adjustment would be offset by an adjustment to valuation allowance. Thus, there would be no impact to the consolidated statements of operations and comprehensive loss if an adjustment were required.

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The Company files income tax returns in the United States federal tax jurisdiction and the Connecticut and Massachusetts state tax jurisdictions. Because the Company has a loss carryforward position, it is generally subject to examination by federal and state tax authorities for all tax years in which a loss carryforward is available.

As of December 31, 2023, the Company has not incurred any material interest or penalty charges.

13. Genevant Agreement

In March 2023, Legacy Korro entered into a collaboration and license agreement (the "Genevant Agreement") with Genevant Sciences GmbH ("Genevant"). Key financial terms under the Genevant Agreement are as follows:

- The Company made a \$2.5 million payment to Genevant in March 2023 upon execution of the Genevant Agreement and recorded the payment within research and development expense in the consolidated statement of operations for the year ended December 31, 2022 December 31, 2023. We also had interest
- The Company will reimburse Genevant for certain out-of-pocket and full-time equivalent costs incurred as a result of research and development activities performed under the Genevant Agreement.
- Genevant is entitled to receive payments from the Company upon the achievement of certain milestones, including potential clinical milestone payments of up to \$13.5 million, potential regulatory and development milestone payments of up to \$27.0 million, and potential commercial milestone payments up to an aggregate total of \$57.0 million.
- Genevant is eligible to receive royalties at percentage rates in the mid-single-digits, based on future annual net sales of licensed products within the scope of the Genevant Agreement.

As of December 31, 2023, no milestones have been achieved and the Company has recorded payments to Genevant of \$1.2 million within research and development expense in the consolidated statement of operations for the year ended December 31, 2022 December 31, 2023.

14. Commitments and Contingencies

Leases

The Company is party to an operating lease at One Kendall Square, Cambridge, Massachusetts and occupies 22,561 square feet of laboratory and office space (the "Kendall Square Facility"). Our interest income On October 20, 2023, the Company entered into an amendment to the Lease Agreement that extended the lease expiration date from December 31, 2023 to September 30, 2024 and interest expense provided the Company with no option to further extend the lease expiration date. The Company is also party to an operating sublease agreement at Cummings Park in Woburn, Massachusetts and occupies 18,148 square feet of laboratory and office space (the "Cummings Park Sublease") which expires on July 31, 2024.

The Company is party to an operating lease for 50,453 square feet of office and laboratory space at 60 First Street, Cambridge, Massachusetts (the "60 First Street Lease"). In May 2023, the Company obtained control over the space and the Company recognized the operating lease right-of-use asset and the operating lease liability of \$26.1 million on the commencement date of the lease. The total rental payments over the 11 year lease are sensitive expected to be \$62.1 million, including rent credits and lease incentives per the terms of the lease. Specifically, the 60 First Street Lease provides the Company with a tenant improvement allowance of \$13.1 million. The Company utilized \$2.3 million of the \$13.1 million tenant improvement allowance as of December 31, 2023. The lease has remaining term approximately 10 years. The Company has an option to extend the lease for an additional period of five years with the rent during the option period being the then fair market rent.

Future minimum lease payments for all three leases, net of \$10.8 million expected to be received and intended to be used related to the remaining tenant improvement allowance and rent credits associated with the 60 First Street Lease, as of December 31, 2023 were as follows (in thousands):

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	As of December 31, 2023
2024	(7)
2025	6
2026	7
2027	7
Thereafter	52
Total Future Minimum Lease Payments	66
Less: Interest	33
Present Value of Operating Lease Liabilities	33

As of December 31, 2023, the weighted average remaining lease term was 10.0 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 11.2%.

The Company combines the lease and non-lease components of fixed costs in its lease arrangements as a single lease component. Variable costs, such as utilities and maintenance costs, are not included in the measurement of right-of-use assets and lease liabilities, but rather are expensed when the event determining the amount of variable consideration to be paid occurs.

The following table summarizes the effect of lease costs in the Company's consolidated statement of operations and comprehensive loss of its operating leases (in thousands):

	Year Ended December 31,	
	2023	2022
Operating lease costs	\$ 5,948	\$ 1
Variable Lease Costs	1,211	
Short-term Lease Costs	921	
Total Lease Costs	\$ 8,080	\$ 3

Legal Contingencies

The Company accrues a liability for legal contingencies when it believes that it is both probable that a liability has been incurred and that the Company can reasonably estimate the amount of the loss. The Company reviews these accruals and adjusts them to reflect ongoing negotiations, settlements, rulings, advice of legal counsel and other relevant information. To the extent new information is obtained and the views on the probable outcomes of claims, suits, assessments, investigations or legal proceedings change, changes in the general level Company's accrued liabilities would be recorded in the period in which such determination is made.

In addition, in accordance with the relevant authoritative guidance, for any matters in which the likelihood of material loss is at least reasonably possible, the Company provide disclosure of the possible loss or range of loss. If a reasonable estimate cannot be made, however, the Company will provide disclosure to that effect. The Company expenses legal costs as they are incurred.

On June 3, 2021 and June 22, 2021, purported stockholders of the Company filed putative class action lawsuits in the U.S. District Court for the District of Massachusetts against the Company and the Company's Chief Executive Officer, President, and Director, David Lucchino. On March 21, 2022, the two lawsuits were consolidated into a single lawsuit, Quinones et al. v. Frequency Therapeutics, Inc. et al. and on May 16, 2022, the Company's Chief Development Officer, Dr. Carl Le Bel, was added as a defendant. The plaintiffs alleged violations of Sections 10(b), 20(a) and Rule 10b5 of the Securities Exchange Act of 1934, as amended (the Exchange Act), due to all false and misleading statements and omissions about the Company's Phase 2a clinical trial (FX-322-202) for its product candidate FX-322 in the Company's public disclosures between October 29, 2020 and March 22, 2021. The lawsuit sought, among other things, damages in connection with the Company's allegedly artificially inflated stock price between October 29, 2020 and March 22, 2021 as a result of those allegedly false and misleading statements and omissions, as well as interest, rates, prior U.S. interest rates. Such instruments carry attorneys' fees and costs. The Company filed a degree motion to dismiss the Amended Complaint on July 15, 2022. On March 29, 2023, the Company's motion to dismiss was granted and the lawsuit was dismissed in its entirety. On April 27, 2023, Plaintiff filed a notice of interest rate risk; how if appeal to the United States Court of Appeals for the First Circuit from the order dismissing the lawsuit. On August 2, 2023, Plaintiff-Appellant submitted its opening brief to the First Circuit. The Company filed its response brief on October 27, 2023. The First Circuit heard oral argument on January 8, 2024, and has not yet issued a change 10% in interest rates were decision on plaintiff's appeal. This matter is at the very early stages of the legal process, and as a result, the Company is not able to estimate range of possible loss. Since an estimate of the possible loss or range of loss cannot be made at this time, no accruals have immediately occurred on December 31, 2023. Such change would not have had a material impact on our financial position or results of operations. We had \$10.0 million of current debt and \$4.2 million non-current outstanding been recorded as of December 31, 2023.

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Indemnifications

The Company indemnifies each of its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity, as permitted under Delaware law and in accordance with the Company's amended and restated certificate of incorporation and bylaws. The term of the indemnification period lasts as long as an officer or director may be subject to any proceeding arising out of acts or omissions of such officer or director in such capacity.

The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director and officer liability insurance. This insurance allows for the transfer of risk associated with the Company's exposure and may enable the Company to recover a portion of any future amounts paid. The Company believes that the value of these potential indemnification obligations is minimal. Accordingly, the Company has not recognized any liabilities relating to these obligations for any period presented.

15. 401(k) Savings Plan

The Company has a defined-contribution savings plan under Section 401(k) of the IRC (the "401(k) Plan"). The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation, subject to statutory limitations. Beginning on April 1, 2022, the Company matches 100% of an employee's 401(k) contributions up to a maximum of 3% of the participant's salary, subject to employer match limitations under the plan. As such, the Company made \$0.5 million and \$0.2 million of matching contributions to the 401(k) Plan during the year ended December 31, 2023 and December 31, 2022, respectively.

16. Related Party Transactions

As a result of Atlas' ownership of the Legacy Korro's Series Seed Preferred Stock, Series A Preferred Stock and Series B Preferred Stock which was exchanged in the Merger for the Company's common stock, Atlas represents an affiliate of the Company. During the years ended December 31, 2023 and 2022, the Company incurred expense and expenses of less than \$0.1 million, respectively, related to consulting services provided by an affiliate of Atlas. As of December 31, 2023 and 2022, the Company had no amounts due to this affiliate.

17. Net Loss per Share

The following common stock equivalents have been excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive:

	Year Ended December 31,	
	2023	2022
Legacy Korro Series Seed Preferred Stock	—	684,739
Legacy Korro Series A Preferred Stock	—	2,029,666
Legacy Korro Series B-1 Preferred Stock	—	1,104,178
Legacy Korro Series B-2 Preferred Stock	—	223,417
Unvested Legacy Korro restricted common stock	—	2,902
Outstanding Legacy Korro stock options	1,323,151	461,100
Outstanding Legacy Korro warrant	8,049	8,049
Total	1,331,200	4,514,051

Item 8. Financial Statements

Basic and **Supplementary Data**, diluted loss per share is computed by dividing net loss by the weighted-average common shares outstanding. The following sets forth the computation of the Company's basic and diluted net loss per share (in thousands, except share and per share data):

	Years Ended December 31,	
	2023	2022
Numerator:		
Net loss	\$ (81,172)	\$ (58,000)
Denominator:		
Weighted-average number of shares outstanding, basic and diluted	1,529,321	255,100
Net loss per share, basic and diluted	\$ (53.08)	\$ (227.00)

Our consolidated financial statements, together with the reports of our independent registered public accounting firms, appear at pages F-1 through F-29 of this Annual Report on Form 10-K for the year ended December 31, 2022. An index of those financial statements is found in Item 15 of Part IV of this Annual Report on Form 10-K

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Item 9. Changes in and Disagreements with With Accountants on Accounting and Financial Disclosure.

None

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," "procedures" as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's SEC's rules and forms forms. Disclosure controls and (2) procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Our In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and our management necessarily applied its judgment in evaluating the cost-benefit relationship benefits of possible controls and procedures. Our disclosure controls and procedures are designed relative to provide reasonable assurance of achieving their control objectives. costs.

Our management, with the participation of our Chief Executive Officer and Vice President, Finance and Operations (our our Chief Financial Officer, who serve as principal executive officer and principal financial officer, respectively), respectively, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2022 December 31, 2023. Based on the such evaluation, of our disclosure controls and procedures as of December 31, 2022, our Chief Executive Officer Vice President, Finance and Operations Chief Financial Officer have concluded that as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

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level as of December 31, 2023.

Management's Annual Report on Internal Control Over over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) reporting. We maintain a system of internal control over financial reporting. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies or procedures may deteriorate. Our internal control over financial reporting is a process designed under the supervision of our principal executive officer and principal financial officer to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our consolidated financial statements for external reporting purposes in accordance with U.S. generally accepted accounting principles.

Our Notwithstanding that we do not qualify for the relief afforded by Instruction 1 to Item 308 of Regulation S-K to newly public companies, management with the participation of Chief Executive Officer and Vice President, Finance and Operations (our principal executive officer and principal financial officer, respectively), conducted an evaluation of the effectiveness of has not assessed nor attested to our internal control over financial reporting based on the criteria as is set forth in "Internal Control – Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations Exchange Act, and Section 404 of the Sarbanes-Oxley Act. Based on the results of the evaluation, we concluded that our internal control over financial reporting was not effective as of December 31, 2023, the end of our last fiscal year. We will do so initially as of December 31, 2024.

We were unable to conduct the required assessment primarily due to the Merger occurring on this evaluation, November 3, 2023 and the resulting substantial change in operational focus, management concluded that the internal control environment. Following the Merger, Legacy Korro's historical operations, and not that of our predecessor business, represent virtually the entirety of the combined business. In addition, following the Merger, our accounting and financial systems, as well as personnel, were replaced by those of Legacy Korro. Due to the extensive changes to our internal control environment, it was impractical for us to develop, implement, assess our system of internal control over financial reporting, was effective and conduct management's assessment of internal control over financial reporting as of December 31, 2022 December 31, 2023.

Changes in Internal Control over Financial Reporting

There Other than changes due to the Merger, there was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that occurred during the period covered by this Annual Report on Form 10-K our most recently completed fiscal quarter that has materially affected, reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

(a) On March 21, 2024, our board of directors established that our 2024 Annual Meeting of Stockholders will be held on Tuesday, June 11, 2024. The record of the determination of stockholders entitled to receive notice of and to vote at our 2024 Annual Meeting will be the close of business on Wednesday, April 17, 2024. Because the date of our 2024 Annual Meeting differs by more than thirty (30) days from the anniversary date of our 2023 Special Meeting in lieu of an Annual Meeting of Stockholders, which was held on November 3, 2023, we are hereby providing notice, pursuant to Rule 14a-5(f) under the Securities Exchange Act of 1934, as amended, of the Exchange Act, of the deadlines for any stockholder proposals pursuant to Rule 14a-8 under the Exchange Act and for any stockholder nomination or proposal pursuant to Rule 14a-8 via this Form 10-K.

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On March 7, 2023 To be considered for inclusion in this year's proxy materials for our 2024 Annual Meeting, stockholder proposals must be submitted in writing by the close of business on Tuesday, April 9, 2024, Christopher Loose, Ph.D., notified to our Corporate Secretary at our principal executive offices at One Kendall Square Building 600-700, Suite 6-401, Cambridge, MA 02139. In addition to complying with this deadline, stockholder proposals intended to be considered for inclusion in the Board proxy materials for our 2024 Annual Meeting must also comply with our bylaws and all applicable rules and regulations promulgated by the Securities and Exchange Commission under the Exchange Act. Additionally, any stockholder who intends to submit a proposal regarding a director nomination or any other matter of Directors business at our 2024 Annual Meeting not to be included in our proxy materials for our 2024 Annual Meeting, must also ensure that notice of any such proposal (including any additional information specified in our bylaws) is received by our Corporate Secretary at our principal executive offices by the Company close of his resignation as the Company's Interim Chief Executive Officer, effective immediately. David Lucchino, the Company's President and Chief Executive Officer, has returned from a temporary medical leave of absence and resumed his position in full as Chief Executive Officer. Dr. Loose will continue to serve in his position as the Company Chief Scientific Officer. business on April 9, 2024.

(b) None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Executive Officers and Directors

The following table sets forth information regarding our Our directors and executive officers and directors their ages as of the date of this Annual Report on Form 10-K. are listed below:

		Position
Name	Age	

Executive Officers:

Executive Officers Ram Aiyar	46	
David L. Lucchino	5	President, Chief Executive Officer Director, and Co-Founder Director
Vineet Agarwal		
Christopher R. Loose, PhD.	42	Chief Scientific Officer and Co-Founder
Carl P. LeBel, Ph.D.	6	Chief Development Financial Officer
Quentin McCubbin	5	
Wendy S. Arnold	3	Chief Manufacturing Officer
	T	
	o	
	d	
	d	
	C	
	h	
	a	
	p	
	p	
	e	
	ll	51
Steve Colletti	58	Chief Scientific Officer
Shelby Walker	49	General Counsel
Non-Employee Directors:		
Non-Employee Directors Ali		
Behbahani (2)(3)	47	
Timothy J. Barberich	7	
	5	Vice Chairperson and Director
Cynthia L. Feldmann	7	
	0	Director
Nessan Bermingham (1)(2)	51	
Michael Huang	4	
	9	Director
Jean-Francois Formela (1)(3)	67	
Robert S. Langer, Sc.D.	7	
	4	Director
Rachel Meyers(3)	60	Director
Timothy Pearson (1)(2)	56	Director
David L. Lucchino		
Joel S. Marcus	7	
	55	Director

-
- (1) Audit Committee member
 - (2) Compensation Committee member
 - (3) Nominating and Corporate Governance Committee member

Executive officers Officers

Ram Aiyar, Ph.D., M.B.A. Dr. Aiyar has served as our Chief Executive Officer and a director since completion of the Merger. Dr. Aiyar previously served as Chief Executive Officer and as a director of Legacy Korro since November 2020, and has served as its President since November 2021. Prior to joining Legacy Korro, Dr. Aiyar co-founded Corvidia Therapeutics, Inc. and most recently served its as Chief Financial Officer from January 2020 to November 2020 and Executive Vice President, Corporate and Business Development from February 2016 to November 2020. Prior to that, Dr. Aiyar held leadership roles in corporate development, product development, research, finance and strategy at BeneVir BioPharma, Inc., BioHealth Innovation, Inc., FlowMetric, Inc., Sofinnova Partners, J.P. Morgan Chase and Jol

& Johnson Pharmaceuticals (NYSE:JNJ). Dr. Aiyar is a co-founder and director of Protean Bio, Inc., a director of Triveni Bio, Inc. and a past director of Avidet Techno Inc. Dr. Aiyar holds an M.B.A. in finance and business strategy from INSEAD (France/Singapore), an M.S. in computer engineering and a Ph.D. in electrical and computer engineering from Drexel University, and a B.E. in electronics engineering from Mumbai University. We believe Dr. Aiyar is qualified to serve on the Board because of his significant operational and senior management experience in the biopharmaceutical industry.

Vineet Agarwal, M.B.A. Mr. Agarwal served as Chief Financial Officer since the Merger and previously served as Chief Financial Officer of Legacy Korro since August 2021. Prior to joining Korro Bio, Mr. Agarwal joined J.P. Morgan Chase & Co. in 2007 and advised healthcare companies on merger & acquisitions, capital raising and strategic initiatives. Mr. Agarwal served as Executive Director, Biotech Investment Banking at J.P. Morgan Chase & Co. from January 2019 until May 2021 and as Vice President, Biotech Investment Banking from January 2016 until January 2019. Mr. Agarwal previously served in numerous leadership roles at J.P. Morgan Chase & Co. across different countries. Mr. Agarwal holds an M.B.A. from the Institute of Management Technology, India, and a Bachelor's degree in finance from Shri Ram College of Commerce, India.

Todd Chappell, M.B.A. Mr. Chappell has served as Chief Operating Officer since the Merger and previously served as Chief Operating Officer of Legacy Korro since August 2023 and previously served as Senior Vice President, Strategy and Portfolio Planning of Korro Bio from March 2021. Before joining Korro Bio, Mr. Chappell served as Chief Executive Officer of Rasio Therapeutics, Inc. from June 2019 until March 2021. Prior to this role, he served as Chief Executive Officer of Perceptive Navigation, LLC from June 2015 until May 2019. Mr. Chappell previously managed a portfolio of start-up pharmaceutical and medical device companies as an entrepreneur in residence at BioHealth Innovation, Inc. Prior to that, Mr. Chappell was a Vice President of Operations at Shape Pharmaceuticals, Inc., a portfolio company of Health Ventures, LLC, where he oversaw all day-to-day operations for the development of a novel HDAC inhibitor for cutaneous t-cell lymphoma. Prior to this role, Mr. Chappell was an Executive Director of New Products at CombinatoRx, Inc., where he led the advancement of three programs

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from assay stage into human clinical studies. Mr. Chappell holds an M.B.A. from Boston University and a B.S. in biology from the University of California, Los Angeles

Steve Colletti, Ph.D. Dr. Colletti served as Chief Scientific Officer since the Merger and previously served as Chief Scientific Officer of Legacy Korro since February 2023. Dr. Colletti most recently served as Senior Vice President of Drug Discovery Research and Development at Zymogen, Inc. from May 2021 to January 2023. Prior to this role, he served as Chief Scientific Officer of Lodo Therapeutics from March 2020 to May 2021 and as Senior Vice President, Head of Research and Development from September 2018 to March 2020. He previously held multiple leadership roles at Merck (NYSE:MRK), including in small molecule, natural products, oligonucleotide, peptide and fusion protein bioconjugate drug discovery, targeting programs in cardiovascular and respiratory disease, diabetes and obesity, immunological disorders, infectious diseases, neuroscience and oncology. Also at Merck, Dr. Colletti built and led the RNA Therapeutics Medicinal Chemistry department and was a core member of multiple development teams responsible for discovering more than a dozen preclinical candidates and advancing them to clinical development. Dr. Colletti is an inventor and author of over 130 patents and publications. Dr. Colletti holds a Ph.D. in chemistry from Boston University and a B.S. in chemistry from Loyola University, and was a National Institutes of Health postdoctoral fellow in chemistry at the Scripps Research Institute.

Shelby J. Walker, M.S., J.D. Ms. Walker has served as Senior Vice President, General Counsel and Corporate Secretary since the Merger and previously served as Senior Vice President, General Counsel and Corporate Secretary of Legacy Korro since May 2023. Ms. Walker most recently served as Senior Vice President and Director of Intellectual Property at CRISPR Therapeutics (Nasdaq:CRSP) from March 2018 to April 2023. She previously served as General Counsel at Ginkgo Bioworks, a synthetic biology company, from May 2016 to March 2018. Prior to this role, she served as Vice President, Associate General Counsel and Chief Intellectual Property Counsel at Dyax Corporation, and previously held intellectual property leadership roles at Novo Nordisk (NYSE:NVO) and ZymoGenetics. Ms. Walker holds a J.D. and L.L.M. in intellectual property law from the University of New Hampshire School of Law, master's degrees in biotechnology and regulatory science from Johns Hopkins University and a B.S. in biotechnology from Worcester Polytechnic Institute.

Non-Employee Directors

Nessan Bermingham, Ph.D. Dr. Bermingham, one of Legacy Korro's co-founders, has served as Chairperson of the Board since completion of the Merger, and previously served as Legacy Korro's Chairman and on its board of directors since November 2021, and previously served as its President and Executive Chairman from November 2018 to November 2021. Dr. Bermingham has been an Operating Partner at Khosla Ventures since December 2021 and has served as Interim Chief Executive Officer of Everyone Medicines since October 2022. Previously, he co-founded and served as President and Chief Executive Officer of Triplet Therapeutics from November 2018 until July 2021. Dr. Bermingham was also a Venture Partner at Atlas Venture from February 2018 until July 2021. Dr. Bermingham also served as Interim Chief Executive Officer of Liberate Bio from October 2022 until February 2023. Prior to that role, Dr. Bermingham co-founded and served as President and Chief Executive Officer of Intellia Therapeutics (Nasdaq:NTLA) from 2014 to 2017. Dr. Bermingham currently serves on the boards of directors of a number of private companies and previously served on the board of Xilio Therapeutics (Nasdaq:XLO). He also previously served as the chair of the board of F-Star Therapeutics prior to its reverse merger and subsequent to its acquisition as a public company, and served on the boards of several private companies. Dr. Bermingham holds a bachelor's degree in genetics from

Queen's University Belfast and a Ph.D. in molecular biology from Imperial College London, and was a Howard Hughes Associate Fellow at Baylor College of Medicine. We believe Dr. Bermingham is qualified to serve on the Board because of his significant leadership and investment experience in the biotech industry.

Ali Behbahani, M.D., M.B.A. Dr. Behbahani has served on the Board since completion of the Merger, and previously served as a member of Legacy Korro's Board of directors since August 2019. Dr. Behbahani joined New Enterprise Associates, Inc., or NEA, in 2007 and is a General Partner on the healthcare team. He previously held positions at The Medicines Company, Morgan Stanley Venture Partners and Lehman Brothers. Dr. Behbahani has served as a member of the board of directors of Moderna Therapeutics, Inc. (Nasdaq:GLUE) since April 2020, Black Diamond Therapeutics (Nasdaq:BDTX) since December 2018, Nkarta, Inc. (Nasdaq:NKTX) since August 2015, CRISPR Therapeutics AG (Nasdaq:CRSP) since April 2015, Arcellx, Inc. (Nasdaq:ACLX) since February 2015, Adaptimmune Therapeutics Plc (Nasdaq:ADAP) since September 2014, CVRx, Inc. (Nasdaq:CVRX) since July 2013, Minerva Surgical, Inc. (Nasdaq:UTRS) since May 2011, and was on the board of Nevro Corp. (NYSE:NEVO) from August 2014 to March 2019, Genoea Biosciences (Nasdaq:GNCA) from February 2018 to May 2022, and Oyster Point Pharma (Nasdaq:OYST) from July 2017 to January 2023. He also serves on a number of private company boards. Dr. Behbahani holds a B.S. in biomedical engineering, electrical engineering and chemistry from Duke University, an M.B.A. from the Wharton School of the University of Pennsylvania and an M.D. from the University of Pennsylvania School of Medicine. We believe Dr. Behbahani is qualified to serve on the Board because of his extensive experience as a public company director and investor in the biotech industry.

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Jean-Francois Formela, M.D., M.B.A. Dr. Formela, one of Legacy Korro's co-founders, has served as a member of the Board since completion of the Merger and previously served on Legacy Korro's board of directors since November 2018. Dr. Formela is currently a partner at Atlas Venture, a life sciences-focused venture capital firm, which he joined in 1993. Dr. Formela is a co-founder and director of IFM Therapeutics, and serves as a director of Ikena Oncology, Inc. (Nasdaq:IKNA), as well as a director of the following private companies: Scorpion Therapeutics, Inc., Sail Bio, Inc., Triveni Bio, Inc. and Travin Bio, Inc. Dr. Formela also previously served as a director of Intellia Therapeutics, Inc. (Nasdaq:NTLA), Spero Therapeutics (Nasdaq:SPRO) and several private companies. Dr. Formela is a member of the Massachusetts General Hospital Innovation Advisory Board and a former trustee of the Boston Institute of Contemporary Art. Dr. Formela began his career as a physician practicing emergency medicine at Mount Sinai Hospital in Paris. He holds an M.D. from the Paris University School of Medicine and an M.B.A. from Columbia University. We believe Dr. Formela's experience as an investor and board member in the life sciences industry, as well as his scientific and medical knowledge, provides him with the qualifications and skills to serve on the Board.

David L. Lucchino has previously served as our President and Chief Executive Officer through completion of the Merger and a member of our board of directors. He has also served on the Board, each since November 2014 and was a co-founder of our Company Frequency with Dr. Robert S. Langer and Dr. Christopher R. Loose. From December 2014 until June 2016, Mr. Lucchino served as the President of Entrega Bio, a biotechnology company focused on oral drug delivery technology. Prior to that, Mr. Lucchino co-founded and cofounded Semprus BioSciences, or Semprus, a biotechnology company, and served as its President and Chief Executive Officer from June 2007 to June 2012. Mr. Lucchino oversaw the development of the company's Semprus lead medical product, which received FDA clearance in 2012. Semprus was acquired by Teleflex, Inc., or Teleflex, in June 2012. Prior to Semprus, Mr. Lucchino worked at the investment firm Polaris Partners. He started his biotech career by Founding LaunchCyte, an investment firm where he was also a Managing Director. Mr. Lucchino is the past chairman of the board of directors of MassBio, a nonprofit organization that represents over 1,500 life science firms and provides services and support for the biotechnology industry in Massachusetts. He is a member of the College of Fellows of the American Institute for Medical and Biological Engineering and was appointed by Massachusetts' Governor Charlie Baker as a member of the Commonwealth's STEM Advisory Council. Mr. Lucchino also served as a trustee of Mt. Auburn Hospital, a Harvard Medical School facility for fifteen years, a trustee of the Multiple Myeloma Research Foundation, and a member of the Board of NOLS (The National Outdoor Leadership School). Mr. Lucchino holds an MBA from the Massachusetts Institute of Technology's Sloan School of Management, an M.S. from the Newhouse School of Journalism at Syracuse University, and a B.A. in Philosophy and Religious Studies from Denison University. We believe Mr. Lucchino is qualified to continue to serve on the Board because of his extensive management experience in the biotechnology and pharmaceutical industry, which qualifies him to serve on our board of directors.

Christopher R. Loose, Ph.D. co-founded our company and has served as our Chief Scientific Officer since January 2016. Prior to our company, Dr. Loose co-founded Semprus with Mr. Lucchino and Dr. Langer and served as its Chief Technology Officer from June 2007 until its acquisition by Teleflex in June 2012. At Semprus, he led the technology team in the development through regulatory clearance of medical products designed to reduce infection and clotting. Prior to Semprus, Dr. Loose worked as a chemical engineer at Merck Research Labs. In 2011, Dr. Loose was awarded the inaugural

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Peter Strauss Entrepreneurial Award from the Hertz Foundation. From 2014 to 2021, Dr. Loose served as an Associate Professor Adjunct of Urology at the Yale School of Medicine and Executive Director of Yale University's Center for Biomedical Innovation and Technology, and he continues to serve as a Lecturer in Yale School of Management. Dr. Loose holds a Ph.D. in Chemical Engineering from MIT and a BSE in Chemical Engineering summa cum laude from Princeton University.

Carl P. LeBel, Ph.D. has served as our Chief Development Officer since March 2018. In 2017, Dr. LeBel founded LeBel Consulting, LLC, a biopharmaceutical consulting company. From February 2009 until November 2016, Dr. LeBel served as the Chief Scientific Officer of Otonomy, Inc., or Otonomy, a biopharmaceutical company.

where he was responsible for all research and development activities. From 2008 to 2009, he served as the President and Chief Executive Officer of Akesis Pharmaceuticals, Inc., or Akesis, a virtual metabolic disorders company. Prior to Akesis, Dr. LeBel served as an Executive Director in a variety of research and development management positions for Amgen, Inc., or Amgen, a biopharmaceutical company. Before joining Amgen, Dr. LeBel served as a Research Scientist at Alkermes, Inc. Dr. LeBel is a scientific fellow of the American Academy of Otolaryngology and a full member of the Association for Research in Otolaryngology, the American Association for the Advancement of Science and the Society of Toxicology. Dr. LeBel is a co-inventor on numerous patents in the field of drug delivery and treatment for otology-related disorders. He was a National Institute of Environmental Health Sciences post-doctoral fellow in Molecular Neurotoxicology at the University of California Irvine. Dr. LeBel holds a Ph.D. in Biomedical Sciences and Toxicology from Northeastern University and a B.S. in Chemistry from the University of Detroit. As a result of our restructuring announced in February 2023, Dr. LeBel will be leaving the Company effective March 31, 2023.

Quentin McCubbin, Rachel Meyers, Ph.D. has served as our Chief Manufacturing Officer since January 2021. He joined our company from Cerevel Therapeutics, Inc., or Cerevel, a clinical-stage biotechnology company, where he served as Head of Technical Operations for two years. Prior to Cerevel, he spent 19 years at Takeda/Millennium Pharmaceuticals in a variety of roles including six years as Vice President of Pharmaceutical Sciences and Global Head of Process Chemistry. He has a career as a chemist, completing a post-doctoral fellowship at Imperial College in London. He earned his B.S. and Ph.D. in Chemistry from Monash University in Australia.

Wendy S. Arnold has served as our Chief People Officer since February 2020. Ms. Arnold previously served as Senior Vice President, Human Resources at Karyopharm Biosciences, Inc., or Kaleido, a healthcare company, where she helped to establish the HR infrastructure, compensation, performance and development programs. Prior to Kaleido, she was the head of the HR business partnership function at Moderna, a biotechnology company, where she helped to lead the HR organization during a period of significant growth, including implementing talent development and engagement initiatives. Prior to that, she was at Celgene Avilomics Research (formerly Avila Therapeutics), where she was responsible for building and developing the HR infrastructure for the company's early research and development division. She also held senior HR positions at Inotek Pharmaceuticals and Amylin Pharmaceuticals. Ms. Arnold received her B.S. from Colorado State University. As a result of our restructuring announced in February 2023, Ms. Arnold will be leaving the Company effective March 31, 2023.

Non-Employee Directors

Timothy J. Barberich Dr. Meyers has served as a member of our board of directors since September 2023. Dr. Meyers previously served as Founder and Chief Scientific Officer at Faze Medicines, Inc. from June 2020 to January 2023. Prior to Faze Medicines, Dr. Meyers served as Entrepreneur-in-Residence at Third Rock Ventures. She also spent over 13 years at Alynham Pharmaceuticals, Inc. from April 2003 to November 2016 and remains an active member of the scientific advisory board. Dr. Meyers also serves on several scientific advisory boards, including the National Advisory Board on Innovation and Entrepreneurship through the Department of Commerce. Rachel is listed as an inventor on many patents and patent applications, and has numerous peer-reviewed publications. Dr. Meyers completed her postdoctoral training at Harvard Medical School in the field of signal transduction and received her Ph.D. at the Massachusetts Institute of Technology in the field of *in vitro* transcription. We believe Dr. Meyers' extensive experience in the biotech industry and her expertise in drug discovery and development, including in RNA-based medicines, provide her with the qualifications and skills to serve on the Board.

Timothy R. Pearson. Mr. Pearson has served on the Board since completion of the Merger, and has served as the Chief Executive Officer of Carrick Therapeutics, a privately held oncology company, since July 2019. Mr. Pearson served as an Executive Vice Chairman, President and the Chief Financial Officer of our board TESCO, Inc., an oncology-focused biopharmaceutical company, from 2014 until its acquisition by GlaxoSmithKline in February 2019. He served as an Executive Vice President, Chief Financial Officer and Treasurer of directors since March 2022. Catalyst Health Solutions, a publicly held pharmacy benefit management company, from 2011 until its acquisition by SXC Health Solutions in 2012. Prior to joining Catalyst Health Solutions, Mr. Barberich Pearson served as the Chief Financial Officer and Executive Vice President of MedImmune, Inc. Mr. Pearson has served on the board of directors of Verastem, GlycoMimetics, Inc. (Nasdaq:GLYC) since 2014 and TScan Therapeutics, Inc. as its chairperson since 2019. Mr. Barberich previously served on the boards of directors for GI Dynamics, Inc. from 2011 to 2021, for Tokai Pharmaceuticals, Inc. from 2009 to 2017, for HeartWare International, Inc. from 2008 to 2016, for Inotek Pharmaceuticals Corporation from 2016 to 2017, and for Neurovance, Inc. from 2010 to 2017. Mr. Barberich is co-founder, and served as the CEO and Chairman of Sepracor Inc. from 1984 to 2009. He holds a B.S. in Chemistry from Kings College. We believe Mr. Barberich's extensive experience in the life sciences industry qualifies him to serve on our board of directors.

Cynthia L. Feldmann has served as a member of our board of directors since September 2020 and is the Chair of our Audit Committee. In March 2022, Ms. Feldmann joined the board of Alexandria Real Estate Equities, Inc., or Alexandria, an urban office real estate investing trust focused on collaborative life science, agtech and technology campuses in AAA innovation cluster locations. She serves on Alexandria's Sciences & Technology Board Committee. Ms. Feldmann has served as a member of the board of directors of UFP Technologies, Inc., or UFPT, since June 2017. She chairs the UFPT Audit Committee and serves on the Nominating & Governance Committee. Since 2005, Ms. Feldmann has served on the board of directors of STERIS PLC, or STERIS, a provider of infection prevention, decontamination, and health science technologies, products and services. She is the Chair of STERIS' Nominating & Governance Committee and previously chaired and is a

current member of the Audit Committee. Ms. Feldmann also served from 2003 to January 2018 on the board of directors of Hanger Inc., or Hanger, a provider of orthopedic and prosthetic services and products, and the largest orthotic and prosthetic managed care network in the U.S. Ms. Feldmann served on the Audit Committee, including as Chair of the Audit Committee, the Compensation Committee and the Quality and Technology Committee of Hanger. Ms. Feldmann currently serves on the board of trustees and as a member of the Finance Committee of Falmouth Academy, an academically rigorous, co-ed college preparatory day school for grades 7 to 12. Ms. Feldmann

previously served as a director and chair of the Audit Committee and as a member of the Nominating & Governance, Compensation, and Quality and Technology Committees of Heartware International, Inc., a medical device company, from 2012 until its acquisition by Medtronic PLC in August 2016. Previously, Ms. Feldmann has a 27-year career in public accounting; she was Partner at KPMG LLP, holding various leadership roles in the firm's Medical Technology and Health Care & Life Sciences industry groups and was National Partner-in-Charge of the Life Sciences practice for Coopers & Lybrand (now PricewaterhouseCoopersLLP) among other leadership positions she held during her career there. Ms. Feldmann was a founding board member of Mass Medic, a Massachusetts trade association for medical technology companies, where she also served as treasurer and as a member of the board's Executive Committee during her tenure from 1997 to 2001. Ms. Feldmann is a retired and holds a Masters Professional Director Certification from the American College of Corporate Directors. We believe Ms. Feldmann's extensive expertise in auditing, accounting, particularly her experience in the life sciences industry, qualifies her to serve on our board of directors.

Michael Huang has served as a member of our board of directors since October 2018. Since 2021, Mr. Huang has served as a member of the board of directors of Windgap Medical, Inc. Mr. Huang has served as a member of the board of directors of Viracta Therapeutics since 2019. Mr. Huang serves as Managing Partner at Tai Capital Management Corporation, a venture capital firm. From 2014 to 2017, Mr. Huang served as Chief Executive Officer of NeuroVive Pharmaceutical Asia, Inc., a biopharmaceutical company. Mr. Huang holds an MBA from Rice University, a M.A. in Chemistry from the University of Texas, Arlington, and a B.S. from the University of Texas, Austin. We believe Mr. Huang's extensive investment experience in the life sciences industry qualifies him to serve on our board of directors.

Robert S. Langer, Sc.D., has served as a member of our board of directors since September 2016. Dr. Langer has served as a David H. Koch Institute Professor at the Massachusetts Institute of Technology since 2005. Dr. Langer currently serves on the board of directors of Moderna, Inc., Seer, Abpro bio and Puretech Health plc and previously served on the board of directors of Momenta Pharmaceuticals, Inc., Kala Pharmaceuticals, Inc., Fibrocell Science, Inc., a publicly held biopharmaceutical company until its acquisition by UCB in April 2020. Mr. Pearson is a Certified Public Accountant and Millipore Corp. Dr. Langer holds dual B.S. degrees in business administration from the University of Delaware and in accounting from the University of Maryland, University College, as well as an M.S. degree in finance from Loyola University College. We believe Mr. Pearson is qualified to serve on the Board because of his experience in the biopharmaceutical industry and his expertise in accounting and financial strategic planning and leadership of complex organizations, and human capital management.

Election of Officers

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Our executive officers are appointed by, and serve at the discretion of, our board of directors. There are no family relationships among any of our directors or executive officers.

Our Board of Directors

Our board of directors currently consists of seven directors divided into three staggered classes, with one class to be elected at each annual meeting to serve a three-year term.

There are no family relationships among any of our directors and officers.

Committees of Our Board of Directors

The standing committees of our board of directors are the following: audit committee, compensation committee and a B.S. in Chemical Engineering from Cornell University. We believe Dr. Langer's pioneering academic work, extensive medical nominating and scientific knowledge, corporate governance committee, and experience serving on public company boards each operate pursuant to a charter. Our board of directors may establish other committees from time to time to serve on time to us and our board of directors.

Joel S. Audit Committee

Our audit committee oversees our corporate accounting and financial reporting process. Among other matters, the audit committee's responsibilities will include

- appointing, approving the compensation of, and assessing the independence of, our independent registered public accounting firm;
- pre-approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the overall audit plan with our independent registered public accounting firm and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- coordinating the oversight and reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;

- recommending, based upon the audit committee's review and discussions with management and our independent registered public accounting firm, w audited financial statements shall be included in our Annual Report on Form 10-K;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements accounting matters;
- preparing the audit committee report required by SEC rules to be included in our annual proxy statement;
- reviewing all related person transactions for potential conflict of interest situations and approving all such transactions; and
- reviewing quarterly earnings releases.

The audit committee consists of Timothy Pearson, Nesson Bermingham and Jean-Francois Formela. Timothy Pearson is the chair of the audit committee and financial expert under the rules of the SEC. To qualify as independent to serve on our audit committee, listing standards of Nasdaq and the applicable SEC rules requi a director not accept any consulting, advisory or other compensatory fee from us, other than for service as a director, or be an affiliated person of us. We believe that t composition of the audit committee complies with the applicable requirements of the rules and regulations of Nasdaq and the SEC.

Compensation Committee

Our compensation committee will oversee policies relating to compensation and benefits of our officers and employees. Among other matters, the compensati committee's responsibilities include:

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- annually reviewing and recommending to the board of directors the corporate goals and objectives relevant to the compensation of our Chief Executive
- evaluating the performance of our Chief Executive Officer in light of such corporate goals and objectives and, based on such evaluation, recommendin of directors the cash compensation of our Chief Executive Officer;
- determining the cash compensation of our other executive officers;
- overseeing and administering our compensation and similar plans;
- reviewing and approving the retention or termination of any consulting firm or outside advisor to assist in the evaluation of compensation matters and e assessing potential and current compensation advisors in accordance with the independence standards identified in the applicable Nasdaq rules;
- retaining and approving the compensation of any compensation advisors;
- reviewing and approving the grant of equity-based awards;
- reviewing and recommending to the board of directors the compensation of our directors; and
- preparing the compensation committee report required by SEC rules, if and when required, to be included in our annual proxy statement.

The compensation committee consists of Nesson Bermingham, Ali Behbahani and Timothy Pearson. Nesson Bermingham is the chair of the compensation committee. Each member of our compensation committee is a "non-employee" director within the meaning of Rule 16b-3 of the rules promulgated under the Exchange and independent within the meaning of the independent director guidelines of Nasdaq. We believe that the composition of the compensation committee complies with applicable requirements of the rules and regulations of Nasdaq.

Nominating and Corporate Governance Committee

The nominating and corporate governance responsibilities include:

- developing and recommending to the board of directors criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by stockholders;
- reviewing the composition of the board of directors to ensure that it is composed of members containing the appropriate skills and expertise to advise t
- identifying individuals qualified to become members of the board of directors;
- recommending to the board of directors the persons to be nominated for election as directors and to each of the board's committees;
- reviewing and recommending to the board of directors appropriate corporate governance guidelines; and
- overseeing the evaluation of the board of directors.

The nominating and corporate governance committee consists of Ali Behbahani, Jean-Francois Formela and Rachel Meyers. Ali Behbahani is the chair of the nominating and corporate governance committee. We believe that the composition of the nominating and corporate governance committee meets the requirements fo independence under, and the functioning of such nominating and corporate governance committee complies with, any applicable requirements of the rules and regula of Nasdaq.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who beneficially own more than 10% of a registered class of our securities, to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. Officers, directors and greater than 10% beneficial owners are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file.

To our knowledge, based solely on our review of Forms 3, 4 and 5, and any amendments thereto, filed by such reporting persons and/ or written representation no Form 5 was required, we believe that during the fiscal year ended December 31, 2023, all filing requirements applicable to our executive officers, directors and persons who beneficially own more than 10%

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percent of a registered class of our equity securities under the Exchange Act were met in a timely manner except for (i) two late Form 4 filings for David L. Lucchino with respect to the vesting of his restricted stock units, or RSUs, and two sales to cover tax withholding obligations in connection with the vesting of the RSUs and (ii) one late Form 4 filing for Richard J. Mitrano with respect to one sale required to cover tax withholding obligations in connection with the vesting of RSUs pursuant to a Rule 10b trading plan.

Code of Business Conduct and Ethics

We have adopted an amended and restated code of business conduct and ethics for directors, officers, and employees, known as the Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics is available on our website at <https://ir.korrobio.com/corporate-governance/governance-overview>. We will promptly disclose on our website (i) the nature of any amendment to the policy that applies to our principal executive officer, principal financial officer, or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals. The name of such person who is granted the waiver and the date of the waiver. Stockholders may request a free copy of the Code of Business Conduct and Ethics from Corporate Secretary, c/o Korro Bio, Inc., One Kendall Square, Building 600-700, Suite 6-401 Cambridge, MA 02139.

Compensation Recovery Policy

In accordance with the requirements of the SEC and Nasdaq listing rules, our board of directors adopted a compensation recovery policy on November 3, 2022, effective as of October 2, 2023. The compensation recovery policy provides that in the event we are required to prepare a restatement of financial statements due to material noncompliance with any financial reporting requirement under securities laws, we will seek to recover any incentive-based compensation that was based upon attainment of a financial reporting measure and that was received by any current or former executive officer during the three-year period preceding the date that the restatement was required if such compensation exceeds the amount that the executive officers would have received based on the restated financial statements. We have filed this policy as an Exhibit to this Annual Report on Form 10-K.

Item 11. Executive Compensation.

On November 3, 2023, Frequency completed the Merger with Legacy Korro. At the effective time of the Merger, the management of Frequency was replaced by the management of Legacy Korro. Unless otherwise indicated, the disclosures in this section regarding Frequency's common stock or securities convertible into common stock for periods or as of a date that precedes the closing of the Merger have been adjusted to give effect to the Reverse Stock Split, and the disclosures in this section regarding Legacy Korro's common stock or securities convertible into Legacy Korro's common stock for periods or as of a date that precedes the closing of the Merger have been adjusted to give effect to the Exchange Ratio and the Reverse Stock Split.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt in the future could vary significantly from our historical practices and currently planned programs summarized in this discussion.

Executive Compensation Overview

This section discusses the material components of the executive compensation program for our named executive officers, which consists of (i) any person who served as our principal executive officer during any part of 2023, (ii) our two most highly compensated executive officers (other than our principal executive officers) who were serving as executive officers on December 31, 2023, and (iii) one additional individual who would have been under clause (ii) but for the fact that he was not serving as an executive officer on December 31, 2023. In 2023, our named executive officers were:

- Ram Aiyar, Ph.D., our Chief Executive Officer and President;
- David L. Lucchino, our former President and Chief Executive Officer;
- Vineet Agarwal, our Chief Financial Officer;
- Steven Colletti, Ph.D., our Chief Scientific Officer; and
- Christopher R. Loose, Ph.D., our former Chief Scientific Officer.

2023 Summary Compensation Table

The following table presents information regarding the total compensation awarded to, earned by and paid to our named executive officers for services during

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)(1)	Option Awards (\$)(2)	Nonequity		Total (\$)
						Incentive Plan Compensation (\$)(3)	All Other Compensation (\$)	
Ram Aiyar Chief Executive Officer and President	2023	498,487	-	-	2,013,364	336,479	9,900(4)	2,856
David L. Lucchino Former President and Chief Executive Officer (5)	2022	472,500	-	-	546,835	170,100	7,110	1,196
David L. Lucchino Former President and Chief Executive Officer (5)	2023	558,767(6)	-	1,338,400	-	-	1,981,098(7)	3,876
Vineet Agarwal Chief Financial Officer	2022	630,000	-	1,209,000	927,028	378,000	15,250	3,156
Vineet Agarwal Chief Financial Officer	2023	426,484	250,000(8)	-	511,121	125,386	9,900(4)	1,322
Steven Colletti Chief Scientific Officer(9)	2022	404,250	-	-	88,676	127,339	8,743	625
Christopher R. Loose Former Chief Scientific Officer (11)	2023	361,667(6)	-	-	1,087,385	151,269	47,047(10)	1,647
Christopher R. Loose Former Chief Scientific Officer (11)	2023	294,211(6)	-	533,358(12)	-	-	752,905(13)	1,586
Christopher R. Loose Former Chief Scientific Officer (11)	2022	480,344	-	604,500	226,580	192,138	15,250	1,516

- Amounts represent the aggregate grant date value of the RSUs granted to our named executive officers during the applicable year, computed in accordance with FASB ASC Topic 718, rather than the amounts paid to or realized by the named executive officer. Such grant date fair values do not take into account forfeitures. The assumptions used in calculating the grant date fair values of the RSUs reported in this column are set forth in Note 11 of our financial statements included elsewhere in this Annual Report on Form 10-K. These amounts reported in this column reflect the accounting cost for these RSUs and do not reflect the economic value that may be received by our named executive officers upon vesting and settlement of such awards or any sale of the shares of our common stock received.
- Amounts represent the aggregate grant date fair value of the stock option awards granted to our named executive officers during the applicable fiscal year, computed in accordance with FASB ASC Topic 718, rather than the amounts paid to or realized by the named executive officer. Such grant date fair values do not take into account any estimated forfeitures. The assumptions used in calculating the grant date fair value of the stock option awards reported in this column are set forth in Note 11 of our financial statements included elsewhere in this Annual Report on Form 10-K. The amounts reported in this column reflect the accounting cost for these stock option awards and do not correspond to the actual economic value that may be received by our named executive officers upon the exercise of such awards or any sale of the underlying shares of our common stock.
- Amounts represent cash incentive compensation awarded in recognition of individual and/or company performance under our annual incentive compensation program. Refer to "—2023 Bonuses" below for additional information.
- Amount reported represents matching contributions to the named executive officer's 401(k) account.
- Mr. Lucchino's employment terminated in connection with the Merger but he continues to provide services to us as a non-employee member of our board of directors.
- Amount reported reflects the prorated base salary for the named executive officer's partial year of service with us during the applicable year.
- The amount reported represents severance paid to Mr. Lucchino in connection with his termination of employment in the amount of \$1,958,224, comprising \$992,250, which represents 18 months of Mr. Lucchino's 2023 base salary, \$333,833, which represents Mr. Lucchino's prorated annual bonus for the 2023 fiscal year, \$396,900, which

represents Mr. Lucchino's target annual bonus for the 2023 fiscal year, \$61,473 in company-paid COBRA premiums, and \$173,768, which represents 18 months of Mr. Lucchino's 2023 base salary.

- the accelerated vesting of Mr. Lucchino's equity awards in connection with his termination of employment as well as \$16,500 in matching contributions under the Frequency 401(k) plan and \$6,374, the compensation earned by Mr. Lucchino for services on our board of directors after the Merger.
8. Amount represents a transaction bonus awarded in connection with the completion of the Merger.
 9. Dr. Colletti was not a named executive officer for 2022.
 10. Amount represents \$9,713 in matching contributions made by us under our 401(k) retirement plan and reimbursement of \$37,334 for expenses incurred in connection with travel to work at our offices and housing in the greater Boston, Massachusetts area.
 11. Dr. Loose departed our company in connection with the Merger.
 12. Amount reported includes \$31,458, which represents the incremental fair value, computed in accordance with FASB ASC Topic 718, related to the amount of Dr. Loose's RSUs in 2023 to accelerate the vesting of such RSUs in connection with termination of Dr. Loose's employment.
 13. The amount reported represents severance paid to Dr. Loose in connection with his termination of employment in the amount of \$736,405, comprised of continued base salary payments, \$201,744, which represents Dr. Loose's target annual bonus for the 2023 fiscal year, and \$30,300 in company-paid life insurance premiums as well as \$16,500 in matching contributions made by us under the Frequency 401(k) plan.

Narrative Disclosure to the 2023 Summary Compensation Table

Prior to the Merger, our compensation committee reviewed compensation annually for all employees, including our executive officers. Following the Merger, our compensation committee anticipates annually reviewing the compensation of our employees, including our executive officers. In setting executive base salaries and bonuses and granting equity incentive awards, the compensation committee considers compensation for comparable positions in the market, the historical compensation levels of our executive officers, individual performance as compared to our expectations and objectives, internal equity, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders, and a long-term commitment to us. We target a general competitive position and consider independent third-party benchmark analytics to determine the mix of compensation of base salary, bonus and long-term incentives.

Our compensation committee is primarily responsible for determining the compensation for our executive officers. Our compensation committee typically reviews and discusses management's proposed compensation with our Chief Executive Officer for all executives other than the Chief Executive Officer. Based on those discussions and its discretion, taking into account the factors noted above, the compensation committee then sets the compensation for each executive officer other than the Chief Executive Officer. For the Chief Executive Officer, our compensation committee determines and approves the compensation, or upon request of the board of directors recommends our Chief Executive Officer's compensation for approval by our board of directors. Our compensation committee may delegate certain authorities to an officer of our company and has delegated to our Chief Executive Officer the authority to make certain equity award grants to employees (other than our executive officers), within specified limits approved by the compensation committee. Our compensation committee has the authority to engage the services of a consulting firm or other outside advisor to assist it in designing our executive compensation programs and in making compensation decisions. During 2023, the compensation committee retained the services of Alpine Rewards LLC, or Alpine, as its external compensation consultant to advise on executive compensation matters including our overall compensation program design and collection of market data to inform our compensation programs for our executive officers and members of our board of directors. Alpine reports directly to our compensation committee. Our compensation committee annually assesses its independence consistent with Nasdaq listing standards and concluded that the engagement of such consultant did not raise any conflict of interest.

2023 Base Salaries

Each of the named executive officers' base salary is a fixed component of annual compensation for performing specific duties and functions. Base salaries are adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience. For the fiscal year ended December 31, 2023, the annual base salaries for Dr. Aiyar, Mr. Lucchino (prior to termination of his employment), Mr. Agarwal, Dr. Colletti, and Dr. Loose (prior to termination of his employment) were \$498,487, \$661,500, \$426,484, \$420,000, and \$504,361, respectively.

2023 Annual Bonuses

During the year ended December 31, 2023, Dr. Aiyar, Mr. Lucchino (prior to termination of his employment), Mr. Agarwal, Dr. Colletti, and Dr. Loose (prior to termination of his employment), were each eligible to earn an annual bonus based on their individual performance and/or our performance as a company. For the year ended December 31, 2023, the target annual

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bonuses for Dr. Aiyar, Mr. Lucchino (prior to termination of his employment), Mr. Agarwal, Dr. Colletti, and Dr. Loose (prior to termination of his employment) were equal to 45%, 60%, 35%, 35%, and 40%, respectively, of their applicable annual base salaries.

Equity Incentive Compensation

Although neither Legacy Korro nor Frequency had a formal policy with respect to the grant of equity incentive awards to its executive officers, we believe that equity awards provide our executive officers with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and stockholders. In addition, we believe that equity awards with a time-based vesting feature promote executive retention because this feature incentivizes our executive officers to remain in our employment during the applicable vesting period. Accordingly, our board of directors periodically reviews the equity incentive compensation of

named executive officers and from time to time may grant equity incentive awards to them. In 2023, we granted options and RSUs to our named executive officers, as described in more detail in the “—Outstanding Equity Awards at Fiscal 2023 Year-End” table below.

Perquisites

We generally do not provide perquisites to our employees, other than certain de minimis perquisites available to all of our employees, including our named executive officers. However, pursuant to his employment agreement with us, Dr. Colletti is also entitled to reimbursement (i) for reasonable expenses incurred in connection with to work at our offices and (ii) up to \$4,000 per month for housing in the greater Boston, Massachusetts area.

401(k) Plan

We maintain the Korro Bio 401K Retirement Plan, a tax-qualified retirement plan that provides eligible employees, including the named executive officers, with opportunity to save for retirement on a tax-advantaged basis. Plan participants are able to defer eligible compensation subject to applicable annual limits under the Code. Participants' pre-tax or Roth contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to participants' directions. Participants are immediately and fully vested in their contributions. We match each participant's contribution up to a maximum of 3% of his or her eligible compensation with participants vesting immediately and fully in such matching contributions. Our 401(k) plan is intended to be qualified under Section 401(a) of the Code with the 401(k) plan's related trust intended to be tax exempt under Section 501(a) of the Code.

Prior to the consummation of the Merger, Frequency maintained a 401(k) retirement savings plan, or the Frequency 401(k) Plan, for Frequency employees. Prior to their respective terminations, Mr. Lucchino and Dr. Loose were eligible to participate in the Frequency 401(k) Plan on the same terms as other full-time Frequency employees. Under this plan, Frequency matched 100% of the first 5% of participants' contributions.

Prior Offer Letters and Employment Agreements

Legacy Korro previously entered into offer letters or employment agreements with Dr. Aiyar, Mr. Agarwal and Dr. Colletti and Frequency previously entered into employment agreements with Mr. Lucchino and Dr. Loose, which were in effect in 2023 prior to the Merger and are described below. We entered new agreements with certain of our named executive officers following the Merger, as described further below.

Ram Aiyar

On October 13, 2020, Legacy Korro entered into an offer letter with Dr. Aiyar, or the Aiyar Offer Letter. The Aiyar Offer Letter sets forth his initial annual base salary of \$450,000, initial target bonus opportunity equal to 40% of Dr. Aiyar's annual base salary, initial equity grant, and his eligibility to participate in our employee benefit plans generally.

The Aiyar Offer Letter provided that in the event that Dr. Aiyar's employment was terminated by Legacy Korro without “cause” or by him for “good reason” (as such terms are defined in the Aiyar Offer Letter), in either case within three months before or 12 months following a change in control, or the Aiyar Change in Control Period, subject to Dr. Aiyar's signing and complying with a separation agreement and release, Dr. Aiyar would be entitled to the following severance benefits: (i) a lump sum cash payment equal to sum of (x) 12 months of his then-current base salary (or the base salary in effect immediately prior to the change in control, if higher), plus (y) 100% of Dr. Aiyar's target annual bonus for the year of termination, without regard to whether the metrics had been established or achieved for such year; (ii) if Dr. Aiyar elected COBRA health continuation, a monthly payment to the group health plan provider or the COBRA provider for up to 12 months, and (iii) 100% of all equity awards held by Dr. Aiyar would have immediately accelerated in vesting and become fully exercisable or non-forfeitable.

In addition, in the event that Dr. Aiyar's employment were terminated by Legacy Korro without “cause” or by him for “good reason”, in either case outside the Aiyar Change in Control Period, subject to Dr. Aiyar's signing and complying with a separation agreement and release, Dr. Aiyar would have been entitled to the severance benefits as described in the preceding paragraph, payable in substantially equal installments over a 12-month period, provided that Dr. Aiyar would not have been

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entitled to any acceleration of vesting of his equity awards and the target annual bonus described above would have been prorated based on the date of termination.

David Lucchino

Frequency entered into a second amended and restated executive employment agreement with Mr. Lucchino on September 20, 2019, pursuant to which Frequency employed Mr. Lucchino as its President and Chief Executive Officer. The employment agreement also provided for Mr. Lucchino to serve as a member of the Frequency board of directors for as long as he was employed as its Chief Executive Officer. The employment agreement had an indefinite term.

The employment agreement provided for an initial annual base salary of \$525,000, which was increased to \$630,000 effective January 1, 2022, and for an initial target annual performance bonus equal to 55%, which was increased to 60% effective January 1, 2021, of Mr. Lucchino's annual base salary based on the attainment of predetermined performance objectives agreed upon between Mr. Lucchino and Frequency's board of directors. In the event of certain corporate transactions, including spin-off of assets or a restructuring, Mr. Lucchino would have been entitled to the same relative ownership percentage in the resulting entity or entities as he had in the company immediately before the corporate transaction. If a “change in control” (as such term is defined in his employment agreement) occurred, all of Mr. Lucchino's equity-based equity awards would accelerate and vest.

On November 1, 2023 and in connection with Mr. Lucchino's departure from Frequency in connection with the Merger, Mr. Lucchino signed a separation agreement pursuant to which he was entitled to receive the following termination payments, subject to his non-revocation of a release in our favor: (i) eighteen months' base salary, 100% of his target annual bonus and (iii) a pro-rated portion of his annual target bonus based on the portion of the year he was employed. The payments under clause (iii) were payable in a single lump sum on the first payroll date following the 60th day after his termination of employment. Mr. Lucchino also received up to twelve months of continued coverage, at our expense, under COBRA, if he elected such continued coverage. In addition to the termination payments, all equity awards granted to Mr. Lucchino accelerated in vesting (including any awards subject to performance-based vesting).

Mr. Lucchino was also party to restrictive covenant agreements, pursuant to which he agreed to refrain from competing with us or soliciting its customers or employees during his employment and for one year following termination of his employment and from disclosing our proprietary information during or at any time following his employment.

Vineet Agarwal

On March 12, 2021, Legacy Korro entered into an employment agreement with Mr. Agarwal, or the Prior Agarwal Employment Agreement. The Prior Agarwal Employment Agreement set forth his initial annual base salary of \$385,000, initial target bonus opportunity equal to 35% of Mr. Agarwal's base salary, initial equity grant and his eligibility to participate in our employee benefit plans generally.

The Prior Agarwal Employment Agreement provided that in the event that Mr. Agarwal's employment were terminated by Legacy Korro without "cause" or by him for "good reason" (as such terms are defined in the Prior Agarwal Employment Agreement), in either case within 12 months following a change in control, or the Agarwal Change in Control Period, subject to Mr. Agarwal's signing and complying with a separation agreement and release, Mr. Agarwal would have been entitled to the following severance benefits: (i) a lump sum cash payment equal to sum of (x) nine months of his then-current base salary (or the base salary in effect immediately prior to the change in control, if higher), plus (y) 100% of Mr. Agarwal's target annual bonus for the year of termination, without regard to whether the metrics had been established or achieved for such year; (ii) if Mr. Agarwal elected COBRA health continuation, a monthly payment to the group health plan provider or the COBRA provider for up to nine months, and (iii) 100% of all equity awards subject to time-based vesting held by Mr. Agarwal would have immediately accelerated in vesting and become fully exercisable or non-forfeitable.

In addition, in the event that Mr. Agarwal's employment were terminated by Legacy Korro without "cause" or by him for "good reason", in each case outside the Agarwal Change in Control Period, subject to Mr. Agarwal's signing and complying with a separation agreement and release, Mr. Agarwal would have been entitled to the severance benefits as described in the preceding paragraph, payable in substantially equal installments over a nine-month period, provided that Mr. Agarwal would not have been entitled to any acceleration of vesting of his equity awards and the target annual bonus described above would have been prorated based on the date of termination.

Steven Colletti

On January 20, 2023, Legacy Korro entered into an employment agreement with Dr. Colletti, or the Prior Colletti Employment Agreement. The Prior Colletti Employment Agreement set forth his initial annual base salary of \$420,000, initial target bonus opportunity equal to 35% of Dr. Colletti's base salary, initial equity grant and his eligibility to participate in our employee benefit plans generally.

The Prior Colletti Employment Agreement provided that in the event that Dr. Colletti's employment were terminated by Legacy Korro without "cause" or by him for "good reason" (as such terms are defined in the Prior Colletti Employment Agreement), in either case within 12 months following a change in control, or the Colletti Change in Control Period, subject to

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Dr. Colletti's signing and complying with a separation agreement and release, Dr. Colletti would have been entitled to the following severance benefits: (i) a lump sum cash payment equal to sum of (x) nine months of his then-current base salary (or the base salary in effect immediately prior to the change in control, if higher), plus (y) 100% of Dr. Colletti's target annual bonus for the year of termination, without regard to whether the metrics had been established or achieved for such year; (ii) if Dr. Colletti elected COBRA health continuation, a monthly payment to the group health plan provider or the COBRA provider for up to nine months, and (iii) 100% of all equity awards subject to time-based vesting held by Dr. Colletti would have immediately accelerated in vesting and become fully exercisable or non-forfeitable.

In addition, in the event that Dr. Colletti's employment were terminated by Legacy Korro without "cause" or by him for "good reason", in each case outside the Colletti Change in Control Period, subject to Dr. Colletti's signing and complying with a separation agreement and release, Dr. Colletti would have been entitled to the severance benefits as described in the preceding paragraph, payable in substantially equal installments over a nine-month period, provided that Dr. Colletti would not have been entitled to any acceleration of vesting of his equity awards and the target annual bonus described above would have been prorated based on the date of termination.

Christopher R. Loose

Frequency entered into an amended and restated employment agreement with Dr. Loose on September 20, 2019, pursuant to which Frequency employed Dr. Loose as its Chief Scientific Officer. Dr. Loose's employment agreement had an indefinite term.

Dr. Loose's employment agreement provided for an annual base salary of \$425,000, which was increased to \$480,344 effective January 1, 2022, and a target annual performance bonus equal to 40% of his base salary, and was based on the attainment of predetermined individual and company performance objectives agreed upon between Dr. Loose and Frequency.

In the event Frequency terminated Dr. Loose's employment without "cause" or he resigned for "good reason" (as such terms are defined in his employment agreement), subject to his execution and non-revocation of a release in our favor, he was entitled to receive the following termination payments: (i) 12 months' continued base salary in equal installments following his termination, (ii) 100% of his target annual bonus paid in a lump sum within 14 days following his execution of the release, (iii) if he made an election, up to twelve months continued coverage under COBRA, with us paying the same portion of the COBRA premiums as we pay for active employees. If such a qualifying termination occurs within twelve months following a "change in control" (as defined in his employment agreement), Dr. Loose's equity interests would have accelerated and vested.

Dr. Loose was a party to restrictive covenant agreements, pursuant to which he has agreed to refrain from competing with us or soliciting our customers or employees during his employment and for one year following termination of his employment and from disclosing our proprietary information during or at any time following his employment.

On July 28, 2023, Frequency entered into a separation agreement with Dr. Loose pursuant to which, in exchange for a general release of claims in our favor, he was entitled to receive (i) continued payment of his base salary for a period of 12 months from July 28, 2023, (ii) continued group health plan coverage under COBRA for up to 12 months, with Frequency paying the portion of the premium that it would pay for active and similarly situated employees, (iii) \$201,744.35, which was equal to 100% of his 2023 target bonus opportunity, and (iv) accelerated vesting of all of his unvested stock options and RSUs, subject to the closing of the Merger prior to or on December 31, 2023.

Current Offer Letters and Employment Agreements

We entered new employment agreements with certain of our executive officers following the closing of the Merger, the terms of which are described below.

Ram Aiyar

On November 10, 2023, we entered into a new employment agreement with Dr. Ram Aiyar, our President and Chief Executive Officer, under the Aiyar Employment Agreement. Under the Aiyar Employment Agreement, Dr. Aiyar has an initial annual base salary of \$498,487 and an initial target bonus opportunity equal to 45% of his annual base salary, he continues to remain eligible for equity grants under our equity incentive plans, and he continues to be eligible to participate in our employee benefit plans generally.

The Aiyar Employment Agreement provides that in the event Dr. Aiyar is terminated without "cause" or he resigns for "good reason" (as such terms are defined therein) outside of the change in control period (which extends from three months prior to a change in control to 12 months following a change in control, as "change in control" is defined therein), subject to signing and complying with a separation agreement and release, which shall include, without limitation, a release of claims, a reaffirmation of restrictive covenants, and in our sole discretion, a one year post-employment noncompetition agreement, then Dr. Aiyar will be entitled to the following severance benefits: (i) 12 months of his then-current base salary, (ii) a pro rata target bonus for the year of termination, without regard to whether the metrics have been established or achieved for such year, and (iii) subject to his copayment of premium amounts at the applicable active employees' rate and proper election to continue COBRA health coverage, up to 12 months of payment of the portion of the premium equal to the amount we would have paid to provide health insurance had he remained employed by us.

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The Aiyar Employment Agreement provides enhanced severance pay and benefits in the event Dr. Aiyar's employment is terminated by us without cause or he resigns for good reason, in each case, within the change in control period. Such enhanced severance pay and benefits consist of (i) a lump sum cash payment equal to the sum of (A) 18 months of Dr. Aiyar's then-current base salary (or the base salary in effect immediately prior to the change in control, if higher) plus (B) 1.5 times Dr. Aiyar's target annual bonus for the then-current year, without regard to whether the metrics have been established or achieved for such year, (ii) subject to his copayment of premium amounts at the applicable active employees' rate and proper election to continue COBRA health coverage, up to 18 months of payment of the portion of the premium equal to the amount we would have paid to provide health insurance had he remained employed by us, and (iii) accelerated vesting of the then-outstanding unvested portion of Dr. Aiyar's stock options and other stock-based awards that are subject solely to time-based vesting and any stock options and other stock-based awards that were granted to him prior to the effective date of the Aiyar Employment Agreement and that are subject to performance-based vesting. The severance pay and benefits described in this paragraph are subject to Dr. Aiyar's delivery of and compliance with a fully effective release of claims.

The payments and benefits under the Aiyar Employment Agreement in connection with a change in control may not be eligible for federal income tax deduction under Section 280G of the Code. These payments and benefits may also be subject to an excise tax under Section 4999 of the Code. If the payments or benefits payable to Dr. Aiyar in connection with a change in control would be subject to the excise tax imposed under Section 4999 of the Code, then those payments or benefits will be reduced if such reduction would result in a higher net after-tax benefit to him.

Dr. Aiyar entered into an Employee Proprietary Information and Inventions Assignment Agreement that contains, among other provisions, nondisclosure of confidential information, invention assignment and nonsolicitation provisions.

Vineet Agarwal

On November 8, 2023, we entered into a new employment agreement with Vineet Agarwal, our Treasurer and Chief Financial Officer, or the Agarwal Employment Agreement. Under Mr. Agarwal's new employment agreement, he has an initial annual base salary of \$426,483, an initial target bonus opportunity equal to 35% of his annual base salary and continues to remain eligible for equity grants under our equity incentive plans, and continues to be eligible to participate in our employee benefit plans generally.

The Agarwal Employment Agreement provides that in the event Mr. Agarwal is terminated without "cause" or he resigns for "good reason" (as such terms are defined therein) outside of the change in control period (which extends from three months prior to a change in control to 12 months following a change in control, as "change in control" is defined therein), subject to him signing and complying with a separation agreement and release, which shall include, without limitation, a release of claim reaffirmation of restrictive covenants, and in our sole discretion, a one year post-employment noncompetition agreement, then Mr. Agarwal will be entitled to the following severance benefits: (i) nine months of his then-current base salary, (ii) a pro rata target bonus for the year of termination, without regard to whether the metrics have been established or achieved for such year, and (iii) subject to his copayment of premium amounts at the applicable active employees' rate and proper election to continue COBRA health coverage, up to nine months of payment of the portion of the premium equal to the amount we would have paid to provide health insurance had he remained employed by us.

The Agarwal Employment Agreement provides enhanced severance pay and benefits in the event Mr. Agarwal's employment is terminated by us without cause or Mr. Agarwal resigns for good reason, in each case, within the change in control period. Such enhanced severance pay and benefits consist of (i) a lump sum cash payment equal to the sum of (A) 12 months of Mr. Agarwal's then-current base salary (or the base salary in effect immediately prior to the change in control, if higher) plus (B) 1.0 times Mr. Agarwal's target annual bonus for the then current year, without regard to whether the metrics have been established or achieved for such year, (ii) subject to his copayment of premium amounts at the applicable active employees' rate and proper election to continue COBRA health coverage, up to 12 months of payment of the portion of the premium equal to the amount we would have paid to provide health insurance had he remained employed by us, and (iii) accelerated vesting of the then outstanding and unvested portion of Mr. Agarwal's stock options and other stock-based awards that are subject solely to time-based vesting. The severance pay and benefits described in this paragraph are subject to Mr. Agarwal's delivery of and compliance with a fully effective release of claims.

The payments and benefits under the Agarwal Employment Agreement in connection with a change in control may not be eligible for federal income tax deduction by us pursuant to Section 280G of Code. These payments and benefits may also be subject to an excise tax under Section 4999 of the Code. If the payments or benefits payable to Mr. Agarwal in connection with a change in control would be subject to the excise tax imposed under Section 4999 of the Code, then those payments or benefits will be reduced if such reduction would result in a higher net after-tax benefit to him.

Mr. Agarwal entered into an Employee Proprietary Information and Inventions Assignment Agreement that contains, among other provisions, nondisclosure of confidential information, invention assignment and nonsolicitation provisions.

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Steven Colletti

On November 8, 2023, we entered into a new employment agreement with Steven Colletti, our Chief Scientific Officer, or the Colletti Employment Agreement. Under Dr. Colletti's new employment agreement, he has an initial annual base salary of \$420,000, an initial target bonus opportunity equal to 35% of his annual base salary (and any incentive bonus for 2023 to be prorated based on Dr. Colletti's days of employment with our company during 2023) and continues to remain eligible for equity grants under our equity incentive plans, and continues to be eligible to participate in our employee benefit plans generally.

The Colletti Employment Agreement provides that in the event Dr. Colletti is terminated without "cause" or he resigns for "good reason" (as such terms are defined therein) outside of the change in control period (which extends from three months prior to a change in control to 12 months following a change in control, as "change in control" is defined therein), subject to signing and complying with a separation agreement and release, which shall include, without limitation, a release of claims, a reaffirmation of restrictive covenants, and in our sole discretion, a one year post-employment noncompetition agreement, then Dr. Colletti will be entitled to the following severance benefits: (i) nine months of his then-current base salary, plus (ii) a pro rata target bonus for the year of termination, without regard to whether the metrics have been established or achieved for such year, and (iii) subject to his copayment of premium amounts at the applicable active employees' rate and proper election to continue COBRA health coverage, up to nine months of payment of the portion of the premium equal to the amount we would have paid to provide health insurance had he remained employed by us.

The Colletti Employment Agreement provides enhanced severance pay and benefits in the event Dr. Colletti's employment is terminated by us without cause or Dr. Colletti resigns for good reason, in each case, within the change in control period. Such enhanced severance pay and benefits consist of (i) a lump sum cash payment equal to the sum of (A) 12 months of Dr. Colletti's then-current base salary (or the base salary in effect immediately prior to the change in control, if higher) plus (B) 1.0 times Dr. Colletti's target annual bonus for the then-current year, without regard to whether the metrics have been established or achieved for such year, (ii) subject to his copayment of premium amounts at the applicable active employees' rate and proper election to continue COBRA health coverage, up to 12 months of payment of the portion of the

premium equal to the amount we would have paid to provide health insurance had he remained employed by us, and (iii) accelerated vesting of the then-outstanding unvested portion of Dr. Colletti's stock options and other stock-based awards that are subject solely to time-based vesting. The severance pay and benefits described in paragraph are subject to Dr. Colletti's delivery of and compliance with a fully effective release of claims.

The payments and benefits under the Colletti Employment Agreement in connection with a change in control may not be eligible for federal income tax deduction pursuant to Section 280G of the Code. These payments and benefits may also be subject to an excise tax under Section 4999 of the Code. If the payments or benefits payable to Dr. Colletti in connection with a change in control would be subject to the excise tax imposed under Section 4999 of the Code, then those payments or benefits will be reduced if such reduction would result in a higher net after-tax benefit to him.

Dr. Colletti entered into an Employee Proprietary Information and Inventions Assignment Agreement that contains, among other provisions, nondisclosure of confidential information, invention assignment and nonsolicitation provisions.

Outstanding Equity Awards at 2023 Fiscal Year-End

The following table sets forth information concerning outstanding equity awards held by each of the named executive officers as of December 31, 2023. For Mr. Aiyar, Agarwal and Colletti, each equity award granted prior to the Merger were under the terms of the Legacy Korro Plan and each equity award granted following the Merger were under the terms of the 2023 Plan. For Mr. Lucchino and Dr. Loose, each equity award granted prior to the Merger were under the terms of the 2019 Plan 2014 Plan and each equity award granted following the Merger were under the terms of the 2023 Plan.

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Name	Option Awards					
	Vesting Commencement Date		Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Ram Aiyar	11/2/2020	(1)	105,007	31,226	11.68	12/31/2023
	1/27/2022	(1)	17,614	19,154	22.75	1/27/2024
	1/1/2023	(1)	—	30,130	20.94	2/1/2024
	11/3/2023	(2)	3,265	153,495	14.98	11/3/2025
David L. Lucchino	—	(3)	8,887	—	168.50	4/1/2024
	—	(3)	1,927	—	168.50	4/1/2024
	—	(3)	1,927	—	168.50	4/1/2024
	—	(3)	14,287	—	107.00	10/1/2024
	—	(3)	4,849	—	107.00	2/1/2025
	—	(3)	3,999	—	107.00	1/1/2026
Vineet Agarwal	5/11/2021	(1)	26,385	14,484	11.68	5/2/2023
	1/27/2022	(1)	2,854	3,107	22.75	1/27/2024
	1/1/2023	(1)	—	2,590	20.94	1/2/2024
	11/3/2023	(2)	969	45,578	14.98	11/3/2025
Steven Colletti	2/21/2023	(1)	—	51,895	21.94	4/1/2024
	11/3/2023	(2)	718	33,760	14.98	11/3/2025
Christopher R. Loose	—	(3)	7,211	—	168.50	2/3/2024
	—	(3)	1,284	—	168.50	2/3/2024
	—	(3)	1,284	—	168.50	2/3/2024
	—	(3)	2,935	—	107.00	2/3/2024
	—	(3)	1,149	—	107.00	2/3/2024
	—	(3)	1,399	—	107.00	2/3/2024

1. 1/4 of the shares subject to the stock option vest on the first anniversary of the vesting commencement date, and 1/48 of the shares subject to the stock option each month thereafter, in each case, subject to the named executive officer's continuous service relationship with us through each applicable vesting c

option is also subject to certain acceleration of vesting provisions as provided in the applicable named executive officer's offer letter or employment agreement, as applicable.

2. 1/48 of the shares subject to the stock option vest each month following the vesting commencement date, in each case, subject to the named executive's continuous service relationship with us through each applicable vesting date. The stock option is also subject to certain acceleration of vesting provisions provided in the applicable named executive officer's offer letter or employment agreement, as applicable.
3. All of the shares subject to the stock option were vested as of December 31, 2023.
4. Dr. Loose's service relationship with Frequency terminated on November 3, 2023. The date reported represents the expiration of the post-termination period of the stock option.

Non-Employee Director Compensation

On November 3, 2023, Frequency completed the Merger with Legacy Korro. At the effective time of the Merger, a majority of the Frequency directors resigned with the exception of David Lucchino, and the remaining director vacancies were replaced by new directors designated by Legacy Korro. Accordingly, we have provided this compensation disclosure with respect to all directors of Frequency and Legacy Korro that served during 2023 and for those non-employee directors of Legacy Korro that were appointed to our Board in connection with the Merger.

We have designed and implemented our compensation program for our non-employee directors to attract, motivate and retain individuals who are committed to our values and goals and who have the expertise and experience that we need to achieve those goals.

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2023 Director Compensation Table

The following table presents the total compensation for each person who served as a non-employee director on our board of directors during 2023. The non-employee directors included in the following table under the heading Current Non-Employee Directors were our non-employee directors as of December 31, 2023. Dr. Aiyar, our Chief Executive Officer and President, did not receive any additional compensation from us for services on our board of directors. Mr. Lucchino, the Chief Executive Officer and President of Frequency prior to the Merger, did not receive any additional compensation from Frequency for services on Frequency's board of directors prior to the Merger or from us for services on our board of directors following the Merger. The compensation received by Dr. Aiyar and Mr. Lucchino, respectively, as our named executive officers is set forth above in "—2023 Summary Compensation Table."

Name	Fees Paid or Earned			Total (\$)
	in Cash	Option Awards	All Other Compensation	
	(\$)	(\$)(1)	(\$)	
Current Non-Employee Directors				
Ali Behbahani (2)	8,445	163,589	-	172,034
Nissan Bermingham (3)	202,137	332,390	-	534,527
Jean-Francois Formela (4)	8,206	163,589	-	171,795
Rachel Meyers (5)	4,231	299,994	-	304,225
Timothy R. Pearson (6)	9,560	163,589	-	173,149
Former Non-Employee Directors				
Timothy J. Barberich (7)	65,285	-	-	65,285
Jordan Baumhardt (8)	-	-	-	-
Hannah Chang (9)	-	-	-	-
Cynthia L. Feldmann (10)	42,120	-	-	42,120
Michael Huang (11)	43,383	-	-	43,383
Omar Khwaja (12)	21,016	-	-	21,016
Robert S. Langer (13)	37,065	-	50,000 (14)	87,065
Joel S. Marcus (15)	17,535	-	-	17,535
Alex Silverstein (16)	-	-	-	-
Colin Walsh (17)	-	-	-	-

1. The amounts reported represent the aggregate grant date fair value of the stock option awards granted to our non-employee directors during fiscal year 2023, computed in accordance with FASB ASC Topic 718, rather than the amounts paid to or realized by the non-employee directors. Such grant date fair value takes into account any estimated forfeitures. The assumptions used in calculating the grant date fair value of the stock option awards reported in this column are set forth in Note 11 of our financial statements included elsewhere in this Annual Report on Form 10-K. The amounts reported in this column reflect the aggregate grant date fair value of the stock option awards granted to our non-employee directors during fiscal year 2023.

for these stock option awards and do not correspond to the actual economic value that may be received by our non-employee directors upon the exercise of stock option awards or any sale of the underlying shares of our common stock.

2. As of December 31, 2023, Dr. Behbahani held options to purchase an aggregate of 16,000 shares of our common stock.
3. As of December 31, 2023, Dr. Bermingham held options to purchase an aggregate of 91,773 shares of our common stock.
4. As of December 31, 2023, Dr. Formela held options to purchase an aggregate of 16,000 shares of our common stock.
5. As of December 31, 2023, Dr. Meyers held options to purchase an aggregate of 12,551 shares of our common stock.
6. As of December 31, 2023, Mr. Pearson held options to purchase an aggregate of 16,000 shares of our common stock.
7. As of December 31, 2023, Mr. Barberich held options to purchase an aggregate of 2,335 shares of our common stock.
8. As of December 31, 2023, Mr. Baumhardt did not hold any options to purchase shares of our common stock.
9. As of December 31, 2023, Dr. Chang did not hold any outstanding equity awards.
10. As of December 31, 2023, Ms. Feldman held options to purchase an aggregate of 1,185 shares of our common stock.
11. As of December 31, 2023, Mr. Huang held options to purchase an aggregate of 888 shares of our common stock.
12. As of December 31, 2023, Dr. Khwaja held options to purchase an aggregate of 3,726 shares of our common stock.

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13. As of December 31, 2023, Dr. Langer held options to purchase an aggregate of 7,737 shares of our Bio common stock.
14. Amounts represent consulting fees paid pursuant to a verbal consulting agreement with us prior to the termination of consulting services upon the closing of the Merger. The agreement entitled Dr. Langer to \$5,000 in consulting fees per month.
15. As of December 31, 2023, Mr. Marcus J.D. held options to purchase an aggregate of 888 shares of our common stock.
16. As of December 31, 2023, CPA Mr. Silverstein did not hold any outstanding equity awards.
17. As of December 31, 2023, Mr. Walsh did not hold any outstanding equity awards.

has

Prior to the Merger

Prior to the Merger, Legacy Korro did not have a formal policy to provide any cash or equity compensation to its non-employee directors for their service on the Legacy Korro board of directors or committees of its board of directors nor did any non-employee director receive any compensation for serving on Legacy Korro's board of directors, except for Dr. Bermingham who received an annual payment of \$187,500 for services on Legacy Korro's board of directors prior to the Merger.

Prior to the Merger, Frequency maintained a compensation program for Frequency non-employee directors, or the Frequency Director Program under which each Frequency non-employee director received the following amounts for their services on our board of directors:

Annual Retainer for Board Membership

\$35,000 for general availability and participation in meetings and conference calls of our Board of Directors

Additional Annual Retainer for Committee Membership

Audit Committee Chairperson:	\$	15,000
Audit Committee member (other than Chairperson):	\$	7,500
Compensation Committee Chairperson:	\$	10,000
Compensation Committee member (other than Chairperson):	\$	5,000
Nominating and Corporate Governance Committee Chairperson:	\$	8,000
Nominating and Corporate Governance Committee member (other than Chairperson):	\$	4,000
Additional Retainer for Chairperson of the Board, Vice Chairperson of the Board, or Lead Independent Director:	\$	30,000

Under the Frequency Director Plan, Frequency non-employee directors were granted an option to purchase 29,693 (prior to the Reverse Stock Split) shares of our common stock upon the director's initial election or appointment to our board of directors and, if the director had served on our board of directors since December 2019, an option to purchase 14,846 (prior to the Reverse Stock Split) shares of our common stock on the date of the annual meeting. The stock options granted to Frequency non-employee directors under the program had an exercise price equal to the fair market value of our common stock on the date of grant and expired not later than ten years after the date of grant. The stock options granted upon a director's initial election or appointment vested in 36 substantially equal monthly installments following the date of grant. The stock options granted annually to directors vested in a single installment on the earlier of the day before the following annual meeting or the first anniversary of the date of grant. In addition, all unvested stock options vested in full upon the occurrence of a change in control.

Director fees under the Frequency Director Program were payable in arrears in four equal quarterly installments not later than the fifteenth day following the first of each calendar quarter, provided that the amount of each payment is Executive Chairman and Founder prorated for any portion of Alexandria Real Estate Equities, L.P. (NYSE: ARE) or Alexandria, a best-in-class, mission-driven life science REIT that pioneered life science real estate from a specialty niche to a mainstream asset class and today is the preeminent and longest-tenured owner, operator, and developer uniquely focused on collaborative life science, agtech, and technology campus AAA innovation cluster locations. Since co-founding the company in 1994, director was not serving as a garage startup with \$19 million in Series A capital and a mission to advance human health, he has led the remarkable growth of Alexandria into an S&P 500 company that as of December 31, 2022 has a total market capitalization of \$35.0 billion and a total equity capitalization of \$24.9 billion that ranks it in the top 10% among all publicly traded U.S. REITs. Alexandria, which celebrated its 25th anniversary as a New York Stock Exchange listed company in May 2022, has a total shareholder return exceeding 1,670% as of December 31, 2022. Mr. Marcus also founded and continues to lead Alexandria Venture Investments, the company's strategic venture capital platform. Since the platform's inception in 1996, it has actively invested in disruptive life science companies as well as promising agrifoodtech, climate innovation, and technology companies that are advancing new, transformative therapeutic modalities and platforms to meaningfully improve human health. Alexandria Venture Investments has been recognized by Silicon Valley Bank as the #1 most active corporate investor in biopharma by new deal volume for six consecutive years and by AgFunder as one of the top five most active U.S. agtech investors for two consecutive years. Mr. Marcus also currently serves on the boards of directors of Applied Therapeutics, Inc. and Intra-Cellular Therapies, Inc.. He earned his undergraduate and Juris Doctor degrees from the University of California, Los Angeles. We believe that Mr. Marcus' extensive experience in the life sciences industry and as a chief executive officer and attorney qualifies him to serve on our board of directors.

Following the Merger

Item 11. Executive Compensation. In connection with the Merger, we adopted a non-employee director compensation policy, or the Korro Director Policy. Under the Korro Director Policy, our non-employee directors are eligible to receive cash retainers (which are payable quarterly in arrears and prorated for partial years of service) and equity awards as set forth below:

The information required by this Item 11 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference. 151

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Annual Retainer for Board Membership		
\$40,000 for general availability and participation in meetings and conference calls of our Board of Directors		
Additional Annual Retainer for Committee Membership		
Audit Committee Chairperson:	\$	15,000
Audit Committee member (other than Chairperson):	\$	7,500
Compensation Committee Chairperson:	\$	10,000
Compensation Committee member (other than Chairperson):	\$	5,000
Nominating and Corporate Governance Committee Chairperson:	\$	8,000
Nominating and Corporate Governance Committee member (other than Chairperson):	\$	4,000
Additional Retainer for Non-Executive Chairperson or Lead Director of the Board:	\$	30,000

In addition, the Korro Director Policy provides that, upon initial election or appointment to the board, each new non-employee director will be granted a non-statutory stock option with a value of \$300,000 (as determined in accordance with the policy and subject to a 16,000 share maximum), or the Director Initial Grant. The Director Initial Grant will vest in substantially equal annual installments over three years, subject to continued service as a non-employee director through the applicable vesting date. At each annual meeting of our stockholders, each non-employee director who has been serving as a non-employee director for at least six months as of such meeting and will continue as a non-employee director following such meeting will be granted an annual award of a non-statutory stock option with a value of \$150,000 (subject to an 8,000 share maximum), or the Director Annual Grant. The Director Annual Grant will vest in full on the earlier of the one-year anniversary of the grant date or on the date of our next annual meeting of stockholders, subject to continued service as a non-employee director through the applicable vesting date. The Director Initial Grant and Director Annual Grants are subject to full accelerated vesting upon the sale of our company. All of the foregoing stock options will be granted with a per share exercise price equal to the fair market value of a share of our common stock on the date of grant and will have a 10 year term.

The aggregate amount of compensation, including both equity compensation and cash compensation, paid to any of our non-employee directors for services as a director in a calendar year period will not exceed \$1,000,000 in the first calendar year such individual becomes a non-employee director and \$750,000 in any other calendar year.

We reimburse all reasonable out-of-pocket expenses incurred by directors for their attendance at meetings of the board or any committee thereof.

Employee directors receive no additional compensation for their service as a director.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information regarding beneficial ownership of our common stock as of February 29, 2024.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Under those rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power with respect to the security, as well as any shares of common stock that the individual or entity has the right to acquire within 60 days of February 29, 2024 the exercise of stock options or other rights. These shares are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Except as noted by footnote, and subject to community property laws where applicable, we believe, based on the information provided to them, that the persons and entities named in the table below have sole voting and investment power with respect to all common stock shown as beneficially owned by them.

The table lists applicable percentage ownership based on 8,020,703 shares of common stock outstanding as of February 29, 2024. The number of shares beneficially owned includes shares of common stock that each person has the right to acquire within 60 days, including upon the exercise of stock options and the vesting of RSUs. These stock options and RSUs shall be deemed to be outstanding for the purpose of computing the percentage of outstanding shares of our common stock except to be owned by such person but shall not be deemed to be outstanding for the purpose of computing the percentage of outstanding shares of the combined organization's common stock expected to be owned by any other person.

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Name of Beneficial Owner	Beneficial Ownership	
	Number	Percent
5% or Greater Stockholders:		
Entities affiliated with Atlas Venture(1)	1,119,292	
Entities affiliated with New Enterprise Associates(2)	1,074,273	
FMR LLC(3)	727,205	
Mutual Fund Series Trust, on behalf of Eventide Healthcare & Life Sciences Fund(4)	546,325	
Entities affiliated with Point72 Asset Management(5)	542,657	
Platanus Investment LLC(6)	540,165	
Entities affiliated with Citadel(7)	529,251	
Entities affiliated with Cormorant Asset Management LP(8)	529,170	
Invus Public Equities, L.P.(9)	419,226	
Directors and Named Executive Officers:		
Vineet Agarwal(10)	38,794	
Ram Aiyar(11)	167,394	
Ali Behbahani	—	
Nissan Bermingham(12)	112,455	
Jean-François Formela	—	
David L. Lucchino(13)	58,026	
Rachel Meyers	—	
Timothy R. Pearson	—	
Steve Colletti (14)	18,726	
Christopher R. Loose	—	
All directors and executive officers as a group (11 persons)(15)	419,816	

* Represents beneficial ownership of less than 1%.

- (1) Consists of (i) 942,075 shares of our common stock held by Atlas Venture Fund XI, L.P., or AVF XI, and (ii) 177,217 shares of our common stock held by Atlas Opportunity Fund II, L.P., or AVO II. Atlas Venture Associates XI, L.P. is the general partner of AVF XI and Atlas Venture Associates XI, LLC is the general partner of AVO II. The members of Atlas Venture Associates XI, L.P. collectively make investment decisions on behalf of Atlas Venture Fund XI, L.P. and AVO II. Jean-François Formela is a member of Atlas Venture Associates XI, LLC and a member of Korro Bio's board of directors. Each of AVF XI, Atlas Venture Associates XI, L.P., and AVO II may be deemed to beneficially own the shares held by AVF XI. Dr. Formela expressly disclaims beneficial ownership of the shares of our common stock held by AVO II.

by AVF XI, except to the extent of his pecuniary interest therein, if any. Atlas Venture Associates Opportunity II, L.P. is the general partner of AVO II, and Atlas Associates Opportunity II, LLC is the general partner of Atlas Venture Associates Opportunity II, L.P. The members of Atlas Venture Associates Opportunity II collectively make investment decisions on behalf of Atlas Venture Associates Opportunity II, LLC. Dr. Formela is a member of Atlas Venture Associates Opportunity II, L.P., and Atlas Venture Associates Opportunity II, LLC may be deemed to beneficially own the share: II. Dr. Formela expressly disclaim beneficial ownership of the shares owned by AVO II, except to the extent of his pecuniary interest therein, if any. The mailing address of Atlas is 300 Technology Square, 8th Floor, Cambridge, MA 02139.

- (2) Consists of 1,072,936 shares of our common stock held by New Enterprise Associates 17, L.P., or NEA 17, and 1,337 shares of our common stock held by NEA 2019, L.P. The general partner of NEA 17 is NEA Partners 17, L.P., or NEA Partners 17, and the general partner of NEA Partners 17 is NEA 17 GP, LLC, or NEA 17 GP. The managers of NEA 17 LLC are Forest Baskett, Ali Behbahani, M.D., Carmen Chang, Anthony A. Florence, Jr., Mohamad H. Makhzoumi, Edward T. Mathers, Sandell, Paul Walker and Rick Yang. Dr. Behbahani is a member of NEA 17 LLC and a member of Korro Bio's board of directors. Each of NEA Partners 17 and NEA 2019 may be deemed to beneficially own the shares held by NEA 17. The general partner of NEA Ventures 2019, L.P., or Ven 2019, is Karen Welsh. The address of the principal business office of NEA 17, NEA Partners 17, NEA 17 LLC, Ven 2019, and Mr. Sandell is New Enterprise Associates, 1954 Greenspring Drive, Suite 600, Timonium, MD 21103. The address of the principal business office of Dr. Behbahani, Mr. Baskett, Ms. Chang, Mr. Makhzoumi, Mr. Walker and Mr. Yang is New Enterprise Associates, 1954 Greenspring Drive, Suite 600, Timonium, MD 21103. The address of the principal business office of Mr. Florence and Mr. Mathers is New Enterprise Associates, 100000, 19th Floor, New York, NY 10001.

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- (3) Consists of (i) 180,884 shares of our common stock held by Fidelity Select Portfolios: Biotechnology Portfolio, (ii) 40,253 shares of our common stock held by Fidelity Growth Company Fund, (iii) 197,128 shares of our common stock held by Fidelity Mt. Vernon Street Trust: Fidelity Growth Company Fund, (iv) 250,912 shares of our common stock held by Fidelity Growth Company Commingled Pool and (v) 58,028 shares of our common stock held by Fidelity Growth Company K6 Fund. All of the foregoing securities are beneficially owned, or may be deemed to be beneficially owned, by FMR LLC, its subsidiaries and affiliates, and other companies. Abigail P. Johnson is a Director, the Chairman and the Chief Executive Officer of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the total voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares of FMR LLC, the Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a group with respect to FMR LLC. The address of FMR LLC is 245 Summer Street, Boston, MA 02210.
- (4) Consists of 546,325 shares of our common stock held by Mutual Fund Series Trust, on behalf of Eventide. Eventide Asset Management, LLC is the investment manager of Eventide Asset Management, LLC. In their corporate capacity for Eventide Asset Management, LLC, Mr. John and Dr. Kuruvilla hold voting and/or control over the shares held by Eventide. Mr. John and Dr. Kuruvilla disclaim beneficial ownership of such shares except to the extent of their pecuniary interest therein. The address for Eventide, Mr. John and Dr. Kuruvilla is U.S. Bank Trust Services, Physical Processing, MK-WI S302, 1555 N RiverCenter Drive, Suite 302, Milwaukee, WI 53212.
- (5) Consists of 276,831 shares of our common stock held by Point72 Biotech Private Investments, LLC, or Point72 Biotech, and 265,826 shares of our common stock held by Point72 Associates, LLC, or Point72 Associates. Differentiated Ventures Investments, LLC, or Differentiated Ventures, is the managing member of Point72 Biotech and may be deemed to share beneficial ownership of the shares held by Point72 Biotech. 72 Investment Holdings, LLC, or 72 Investment Holdings, is the sole member of Point72 Associates and may be deemed to share beneficial ownership of the shares of which Differentiated Ventures may be deemed to share beneficial ownership. Steven A. Cohen, or Mr. Cohen, is the sole member of 72 Investment Holdings and may be deemed to share beneficial ownership of the shares of which 72 Investment Holdings may be deemed to share beneficial ownership. Each of Differentiated Ventures, 72 Investment Holdings and Mr. Cohen disclaims beneficial ownership of the shares held by Point72 Biotech. Pursuant to an investment management agreement, Point72 Asset Management, L.P., or Point72 Asset Management, maintains and voting power with respect to the shares held by Point72 Associates and therefore may be deemed to share beneficial ownership of such shares. Point72 Capital Advisors, Inc., or Point72 Capital Advisors, is the general partner of Point72 Asset Management and may be deemed to share beneficial ownership of the shares of which Point72 Asset Management may be deemed to share beneficial ownership. Mr. Cohen is the sole member of Point72 Capital Advisors and may be deemed to share beneficial ownership of the shares of which Point72 Capital Advisors may be deemed to share beneficial ownership. Each of Point72 Asset Management, Point72 Capital Advisors and Mr. Cohen disclaims beneficial ownership of the shares held by Point72 Associates. The address for Point72 Biotech and Point72 Associates is 72 Cummings Point Road, Stamford, CT 06902.
- (6) Consists of 540,165 shares of our common stock held by Platanus Investment LLC, or Platanus. Xinyi Cai is the director of Platanus and holds voting and control over the securities owned by Platanus. The address for Platanus is 3 E 3rd Ave, Suite 200, San Mateo, CA 94401.
- (7) Based solely on Schedule 13G jointly filed by Citadel Advisors LLC, or Citadel Advisors, Citadel Advisors Holdings LP, or CAH, Citadel GP LLC, or CGP, Citadel Securities, Citadel Securities Group LP, or CALC4, Citadel Securities GP LLC, or CSGP, and Mr. Kenneth Griffin, or collectively with Citadel Advisors, Citadel Securities, CALC4 and CSGP, the Citadel Reporting Persons, with respect to shares owned by Citadel Multi-Strategy Equities Master Fund Ltd. Islands company, or CM, Citadel CEMF Investments Ltd., a Cayman Islands limited company, or CCIL, Citadel Securities and CRBU Holdings LLC, a Delaware limited liability company, or CRBH. Citadel Advisors is the portfolio manager for CM and CCIL. CAH is the sole member of Citadel Advisors. CGP is the general partner of CALC4 and is the non-member manager of Citadel Securities and CRBH. CSGP is the general partner of CALC4. Mr. Griffin is the President and Chief Executive Officer and owns a controlling interest in CGP and CSGP. The address of each of the Citadel Reporting Persons is Southeast Financial Center, 200 S. Biscayne Blvd, Miami, FL 33131.
- (8) Consists of (i) 312,052 shares of our common stock held by Cormorant Global Healthcare Master Fund, LP, or Master Fund, and (ii) 217,118 shares of our common stock held by Cormorant Private Healthcare Fund II, LP, or Fund II. Cormorant Global Healthcare GP, LLC, or Global GP, and Cormorant Private Healthcare GP II, LP, or GP II, serve as the general partner of Master Fund and Fund II, respectively. Cormorant Asset Management, LP serves as the investment manager to Master Fund II. Bihua Chen serves as the managing member of Global GP, Private GP II and Cormorant Asset Management, LP. Each of Global GP, Private GP II, Cormorant Asset Management, LP and MS.

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Chen disclaims beneficial ownership of such shares except to the extent of any pecuniary interest therein. The principal address for the Cormorant Asset Management entities is 200 Clarendon Street 52nd Floor, Boston, Massachusetts 02116.

- (9) Consists of 419,226 shares of our common stock held by Invus Public Equities L.P., or Invus. Invus Public Equities Advisors, LLC, or Invus PE Advisors, controls its general partner and accordingly, may be deemed to beneficially own the shares held by Invus. The Geneva branch of Artal International S.C.A., or Artal International Management, as the managing partner of Artal International, controls Artal International and accordingly, may be deemed to beneficially own the shares that Artal International may be deemed to beneficially own. Artal Group S.A., or Artal Group, as the sole stockholder of Artal International Management, controls Artal International Management and accordingly, may be deemed to beneficially own the shares that Artal International Management may be deemed to beneficially own. Westend S.A., or Westend, as the parent company of Artal Group, controls Artal Group and accordingly, may be deemed to beneficially own the shares that Artal Group may be deemed to beneficially own. Stichting Administratiekantoor Westend, or the Stichting, as majority shareholder of Westend, controls Westend and accordingly, may be deemed to beneficially own the shares that Westend may be deemed to beneficially own. Mr. Amaury Wittouck, as the sole member of the board of the Stichting and accordingly, may be deemed to beneficially own the shares that the Stichting may be deemed to beneficially own. The address for Invus and Invus PE Advisors is 750 Lexington Avenue, 30th Floor, New York, NY 10022. The address for Artal International, Artal International Management, Artal Group, Westend, or Westend, is Valley Park, 44, Rue de la Vallée, L-2661, Luxembourg. The address for the Stichting is Claude Debussylaan, 46, 1082 MD Amsterdam, The Netherlands. The address for Invus is 750 Lexington Avenue, New York, NY 10022.
- (10) Consists of 38,794 shares of our common stock underlying options that are exercisable or will become exercisable within 60 days of February 29, 2024.
- (11) Consists of (i) 4,613 shares of our common stock held by The Ram Aiyar Irrevocable Trust, or the Trust, and (ii) 162,781 shares of our common stock underlying options that are exercisable or will become exercisable within 60 days of February 29, 2024. The address of the Trust is c/o Steven M. Burke, P.O. Box 326, Manchester, NH 03103.
- (12) Consists of (i) 35,114 shares of our common stock and (ii) 77,341 shares of our common stock underlying options that are exercisable or will become exercisable within 60 days of February 29, 2024.
- (13) Consists of (i) 22,150 shares of our common stock and (ii) 35,876 shares of our common stock underlying options that are exercisable or will become exercisable within 60 days of February 29, 2024.
- (14) Consists of 18,726 shares of our common stock underlying options that are exercisable or will become exercisable within 60 days of February 29, 2024.
- (15) Consists of (i) 61,877 shares of our common stock and (ii) 357,939 shares of our common stock underlying options that are exercisable or will become exercisable within 60 days of February 29, 2024.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information as of December 31, 2023 with respect to the shares of our common stock that may be issued under our existing equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights		Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities in Plans with Reserved Shares)
		Exercise Price of	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities in Plans with Reserved Shares)	
Equity compensation plans approved by stockholders ⁽¹⁾	1,328,229 ⁽²⁾	\$16.48 ⁽³⁾		344,100
Equity compensation plans not approved by stockholders	—	—		—
Total	1,328,229	\$ 16.48		344,100

- (1) Includes the following plans: the 2023 Plan, the 2019 Plan, the Legacy Korro Plan, the 2014 Plan and the 2023 ESPP.
- (2) Includes 1,328,229 shares issuable upon the exercise of outstanding options, of which 600,977 were assumed in connection with the Merger.
- (3) The weighted average exercise price is calculated based solely on outstanding stock options.
- (4) As of December 31, 2023, a total of 255,694 shares were reserved for issuance pursuant to the 2023 Plan and a total of 88,502 shares were reserved pursuant to the 2023 ESPP. Following the Merger, we did not grant any awards under the 2019 Plan, the 2014 Plan, or the Legacy Korro Plan, but all awards under such plans continue to be governed by their existing terms. The 2023 Plan has an evergreen provision that allows for an annual increase in the number of shares available for issuance under the 2023 Plan to be added on the first day of January,

starting with January 1, 2024, in an amount equal to the lesser of (i) 5% of the outstanding number of shares of our common stock on the immediately preceding December 31 or (ii) such number of shares as determined by the administrator of the 2023 Plan in each case subject to adjustment in the event of a stock dividend or other change in our capitalization. The information required shares of common stock underlying any awards granted under the Legacy Korro Plan or the 2014 Plan that are forfeited, canceled, reacquired by this Item 12 us prior to vesting, satisfied without the issuance of stock, or otherwise.

terminated (other than by exercise) and the shares of common stock that are withheld upon exercise of a stock option or settlement of such award to exercise price or tax withholding will be included added to the shares of common stock available for issuance under the 2023 Plan. The 2023 ESPP has an evergreen provision that allows for an annual increase in the number of shares available for issuance under the 2023 ESPP to be added on the first day of January, starting with January 1, 2024, by the lesser of (i) 88,502 shares of our common stock, (ii) 1% of the outstanding number of shares of common stock immediately preceding December 31, or (iii) such number of shares of common stock as determined by the administrator of the 2023 ESPP. The number of shares reserved under the 2023 ESPP is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization. The number in the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

table does not include the increases from January 1, 2024.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Series B Convertible Preferred Stock Financing

In November 2021, December 2021 and March 2023, Legacy Korro sold an aggregate of 43,085,531 shares of its Series B preferred stock at a purchase price of \$2.61 and \$2.78 per share for aggregate gross proceeds of \$116.0 million. The following table summarizes purchases of Legacy Korro's Series B preferred stock by third parties (share amounts have not been updated to reflect the exchange for our common stock in the Merger):

Participant	Shares of Legacy Korro Series B Preferred Stock	Total Purchase Price (\$)
Atlas Venture Fund XI, L.P. (1)	3,064,273	8,250,001
New Enterprise Associates 17, L.P. (2)	2,971,416	8,000,000
Platanus Investment LLC (3)	1,764,279	4,750,002
Qiming U.S. Healthcare Fund II, L.P. (4)	1,114,281	3,000,000
Mutual Fund Series Trust, on behalf of Eventide Healthcare & Life Sciences Fund (5)	7,428,540	20,000,000
Invus Public Equities, L.P. (6)	5,571,405	15,000,000
Point72 Biotech Private Investments, LLC (7)	5,571,405	15,000,000
The Ram Aiyar Irrevocable Trust (8)	92,857	250,001
FMR LLC (9)	9,285,675	25,000,000
Citadel Multi-Strategy Equities Master Fund Ltd. (10)	835,710	2,249,998
Entities affiliated with Cormorant Asset Management LP (11)	835,710	2,249,998

- (1) Atlas beneficially owned more than 5% of Legacy Korro's capital stock and beneficially owns more than 5% of our outstanding capital stock. Jean-François Fortin is a Partner at Atlas and a member of our board of directors.
- (2) NEA beneficially owned more than 5% of Legacy Korro's capital stock and beneficially owns more than 5% of our outstanding capital stock. Ali Behbahani is a Managing Director at NEA and a member of our board of directors.
- (3) Platanus beneficially owned more than 5% of Legacy Korro's capital stock and beneficially owns more than 5% of our outstanding capital stock. Hannah Chan is a Managing Director at Platanus and was a member of Legacy Korro's board of directors.
- (4) Qiming beneficially owned more than 5% of Legacy Korro's outstanding capital stock and had a designee on Legacy Korro's board of directors.
- (5) Mutual Fund Series Trust, on behalf of Eventide Healthcare & Life Sciences Fund, or Eventide, beneficially owned more than 5% of Legacy Korro's capital stock and beneficially owns more than 5% of our outstanding capital stock.
- (6) Invus Public Equities, L.P. beneficially owned more than 5% of Legacy Korro's capital stock and beneficially owns more than 5% of our outstanding capital stock.
- (7) Point72 Biotech Private Investments, LLC beneficially owned more than 5% of Legacy Korro's capital stock and beneficially owns more than 5% of our outstanding capital stock and had a designee on Legacy Korro's board of directors.
- (8) Ram Aiyar is the grantor of The Ram Aiyar Irrevocable Trust, is our chief executive officer and member of our board of directors and was chief executive officer of Legacy Korro and a member of its board of directors.
- (9) FMR LLC beneficially owned more than 5% of Legacy Korro's capital stock and beneficially owns more than 5% of our outstanding capital stock.

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- (10) Citadel Multi-Strategy Equities Master Fund Ltd. beneficially owned more than 5% of Legacy Korro's capital stock and beneficially owns more than 5% of our outstanding capital stock.
- (11) Entities affiliated with Cormorant Asset Management LP beneficially owned more than 5% of Legacy Korro's capital stock and beneficially own more than 5% of our outstanding capital stock.

Pre-Closing Financing

Legacy Korro entered into a Subscription Agreement in July 2023 with certain investors to consummate the Pre-Closing Financing. Pursuant to the Subscription Agreement, the investors agreed to purchase shares of Legacy Korro common stock, at a price of \$2.78 per share, for aggregate gross proceeds of \$117.3 million. See the investors or their affiliates were beneficial holders of more than 5% of Legacy Korro's capital stock, and the table below sets forth the number of shares of Legacy common stock purchased by such holders at the closing of the Pre-Closing Financing (share amounts have not been updated to reflect the exchange for our common in the Merger):

Participant	Shares of Legacy Korro Common Stock	Total Purchase Price (\$)
Atlas Venture Fund XI, L.P. (1)	177,217	9,999,999
New Enterprise Associates 17, L.P. (2)	177,217	9,999,999
FMR LLC (3)	265,826	14,999,999
Citadel CEMF Investments Ltd.(4)	265,826	14,999,999
Platanus Investment LLC (5)	8,860	500,000
Qiming U.S. Healthcare Fund II, L.P. (6)	35,443	1,999,999
Mutual Fund Series Trust, on behalf of Eventide Healthcare & Life Sciences Fund (7)	177,217	9,999,999
Invus Public Equities, L.P (8)	141,774	8,000,000
Point72 Associates, LLC (9)	265,826	14,999,999
Entities affiliated with Cormorant Asset Management LP (10)	265,826	14,999,999
(1) Atlas beneficially owned more than 5% of Legacy Korro's capital stock and beneficially owns more than 5% of our outstanding capital stock. Jean-François Fo Partner at Atlas and a member of our board of directors.		
(2) NEA beneficially owned more than 5% of Legacy Korro's capital stock and beneficially owns more than 5% of our outstanding capital stock. Ali Behbahani is a NEA and a member of our board of directors.		
(3) FMR LLC beneficially owned more than 5% of Legacy Korro's capital stock and beneficially owns more than 5% of our outstanding capital stock.		
(4) Citadel beneficially owned more than 5% of Legacy Korro's capital stock and beneficially owns more than 5% of our outstanding capital stock.		
(5) Platanus beneficially owned more than 5% of Legacy Korro's capital stock and beneficially owns more than 5% of our outstanding capital stock. Hannah Chan at Platanus and was a member of Legacy Korro's board of directors.		
(6) Qiming beneficially owned more than 5% of Legacy Korro's outstanding capital stock and had a designee on Legacy Korro's board of directors.		
(7) Eventide beneficially owned more than 5% of Legacy Korro's capital stock and beneficially owns more than 5% of our outstanding capital stock.		
(8) Invus Public Equities, L.P. beneficially owned more than 5% of Legacy Korro's capital stock and beneficially owns more than 5% of our outstanding capital stock.		
(9) Point72 Biotech Private Investments, LLC, an affiliate of Point72 Associates, LLC, beneficially owned more than 5% of Legacy Korro's capital stock and beneficially owns more than 5% of Legacy Korro's outstanding capital stock and had a designee on Legacy Korro's board of directors.		
(10) Entities affiliated with Cormorant Asset Management LP beneficially owned more than 5% of Legacy Korro's capital stock and beneficially own more than 5% of our outstanding capital stock.		

Other Agreements with Our Stockholders

In connection with Legacy Korro's Series B convertible preferred stock financing, Legacy Korro entered into investors' rights, voting and right of first refusal and sale agreements containing registration rights, information rights, voting rights and rights of first refusal, among other things, with certain holders of Legacy Korro preferred stock and certain holders of Legacy Korro common stock. These stockholder agreements terminated upon the closing of the Merger, except for the registration rights granted under Legacy Korro's investors' rights agreement.

Indemnification Agreements

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We have entered into agreements to indemnify our directors and executive officers. These agreements will, among other things, require us to indemnify these individuals for certain expenses (including attorneys' fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in our right, on account of any services undertaken by such person on our behalf or that person's status as a member of our board of directors to the maximum extent allowed under Delaware law.

Registration Rights under Frequency Investors' Rights Agreement

Frequency entered into a second amended and restated investors' rights agreement, or the Investors' Rights Agreement, in July 2019 with each holder of Frequency preferred stock, which included certain holders of more than 5% of Frequency common stock at the time and certain of Frequency's directors and executive officers. The

Investors' Rights Agreement grants the parties thereto certain registration rights in respect of the "registrable securities" held by them, which securities include (1) the of Frequency common stock issuable or issued upon the conversion of shares of Frequency convertible preferred stock, (2) any shares of Frequency common stock, and (3) any shares of Frequency common stock issued as a dividend or other distribution with respect to, or in exchange for, or in replacement of, the shares described in the foregoing clauses (1) and (2). The registration of shares of Frequency common stock pursuant to the exercise of these registration rights would enable holders thereof to sell such shares under the Securities Act when the applicable registration statement is declared effective. Under the Investors' Rights Agreement, Frequency will pay all expenses relating to such registrations, including the reasonable fees of one special counsel for the participating stockholders, and the stockholders will pay all underwriting discounts and commissions relating to the sale of their shares. The Investors' Rights Agreement also includes customary indemnification and procedural terms.

Form S-1 registration rights

If at any time the holders of at least 40% of the registrable securities request in writing that Frequency effects a registration with respect to at least 25% of such registrable securities then outstanding (or a lesser percent if the anticipated aggregate offering price, net of selling expenses, would exceed \$10.0 million), Frequency is obligated to register their shares. Frequency is obligated to effect at most two registrations in response to these demand registration rights. If the holders requesting registration intend to distribute their shares by means of an underwriting, the managing underwriter of such offering will have the right to limit the numbers of shares to be underwritten for reasons related to the marketing of the shares.

Piggyback registration rights

If at any time Frequency proposes to register any shares of Frequency common stock under the Securities Act, subject to certain exceptions, the holders of registrable securities will be entitled to notice of the registration and to include their registrable securities in the registration. If Frequency's proposed registration involves underwriting, the managing underwriter of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares.

Form S-3 registration rights

If, at any time after Frequency becomes entitled under the Securities Act to register Frequency's shares on a registration statement on Form S-3, the holders of registrable securities request in writing that Frequency effects a registration with respect to registrable securities at an aggregate price to the public in the offering of at least \$1,000,000, net of expenses borne by the holders, Frequency is obligated to effect such registration. Frequency is not obligated to effect more than one S-3 registration in any 12 month period.

Expenses and indemnification

Ordinarily, other than underwriting discounts and commissions, Frequency will be required to pay all expenses incurred by Frequency related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all registration, filing and qualification fees, printing and accounting fees, fees and disbursements of Frequency's counsel, and reasonable fees and disbursements of a counsel for the selling securityholders. Additionally, Frequency has agreed to indemnify and hold harmless the selling stockholders for damages, and any legal or other expenses reasonably incurred, arising from or based upon any untrue statement or alleged untrue statement of material fact contained in any registration statement, an omission or alleged omission to state a material fact required to be stated in any registration statement or necessary to make the statements therein not misleading, or any violation or alleged violation by the indemnifying party of securities laws, subject to certain exceptions.

Termination of registration rights

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The registration rights expire on the earlier of (1) the date that is five years after the closing of Frequency's IPO and (2) with respect to each stockholder, at such time as such stockholder can sell all of its shares pursuant to Rule 144 of the Securities Act or another similar exemption under the Securities Act during any three month period without registration.

Registration Rights under Legacy Korro Investors' Rights Agreement

Legacy Korro entered into a third amended and restated investors' rights agreement, or the Legacy Korro Investors' Rights Agreement, in November 2021 with the holder of Legacy Korro's preferred stock. The information required by the Legacy Korro Investors' Rights Agreement grants such holders certain registration rights in respect of "registrable securities" held by them, which securities include (1) the SEC shares of Legacy Korro's common stock issuable or issued upon the conversion of shares of Legacy Korro's preferred stock, (2) any shares of Legacy Korro's common stock, or any common stock issued or issuable upon conversion and/or exercise of any of Legacy Korro's securities acquired by such holders after the date of the Legacy Korro Investors' Rights Agreement.

Agreement, and (3) any shares of Legacy Korro common stock issued as (or issuable upon the conversion or exercise of any warrant, right, or other security that is: as) a dividend or other distribution with respect to, **our 2023 Annual Meeting** or in exchange for, or in replacement of, **Stockholders** the shares described in the foregoing clauses (1) and (2). The registration of shares of Legacy Korro's common stock pursuant to the exercise of these registration rights would enable the holders thereof to such shares under the Securities Act when the applicable registration statement is **incorporated herein** declared effective. Under the Legacy Korro Investors' Rights Agreement, Legacy Korro agreed to pay all expenses relating to such registrations, including the reasonable fees of one special counsel for the selling holders, and the selling holders agreed to pay all underwriting discounts, selling commissions and stock transfer taxes applicable to the sale of the registrable securities, and fees and disbursement of counsel for the selling holders (except as agreed to be paid by **reference**, Legacy Korro). The Legacy Korro Investors' Rights Agreement also includes customary indemnification and procedural terms.

Form S-1 registration rights

If at any time the holders of a majority of the registrable securities request in writing that Legacy Korro effects a registration with respect to at least 50% of such registrable securities then outstanding (or a lesser percent if the anticipated aggregate offering price, net of selling expenses, would exceed \$15.0 million), Legacy Korro is obligated to register their shares. Legacy Korro is obligated to effect at most two registrations in response to these demand registration rights. If the holders requesting registration intend to distribute their shares by means of an underwriting, the managing underwriter of such offering will have the right to limit the numbers of shares to underwritten for reasons related to the marketing of the shares.

Piggyback registration rights

If at any time Legacy Korro proposes to register any shares of Legacy Korro's common stock under the Securities Act, subject to certain exceptions, the holders of registrable securities will be entitled to notice of the registration and to include their registrable securities in the registration. If Legacy Korro's proposed registration involves an underwriting, the managing underwriter of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares.

Form S-3 registration rights

If, at any time after Legacy Korro becomes entitled under the Securities Act to register Legacy Korro's shares on a registration statement on Form S-3, the holders of at least 10% of the registrable securities then outstanding request in writing that Legacy Korro effects a registration with respect to registrable securities at an aggregate net of selling expenses, to the public in the offering of at least \$5,000,000, Legacy Korro is obligated to effect such a registration. Legacy Korro is not obligated to effect more than two S-3 registrations in any 12 month period.

Termination of registration rights

The registration rights expire on the earlier of (1) the date that is five years after the closing of Legacy Korro's IPO, (2) with respect to each stockholder, at such time a stockholder can sell all of its shares pursuant to Rule 144 of the Securities Act or another similar exemption under the Securities Act during any three month period with limitation during a three-month period, and (3) the closing of a deemed liquidation event.

Pre-Closing Financing Registration Rights

In connection with the Pre-Closing Financing, we entered into a registration rights agreement, or the Registration Rights Agreement, in July 2023 with Legacy Korro and each purchaser in the Pre-Closing Financing. Pursuant to the Registration Rights Agreement, we agreed to register the "registrable securities" held by the purchasers on a registration statement, or registration statements, if necessary, to permit resale of such securities on a continuous basis pursuant to Rule 415. The "registrable securities" include (a) all shares of our common stock issued to the purchasers at the closing of the Merger in respect of the shares of Legacy Korro's common stock purchased by the purchasers in the Pre-Closing Financing, (b) all shares of our common stock issued at the closing of the Merger to the purchasers in respect of all other shares of Legacy Korro's capital stock held by

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purchaser as of immediately prior to the closing of the Merger, and (c) any securities issued or then issuable upon any stock split, dividend or other distribution, recapitalization or similar event with respect to the foregoing. Under the Registration Rights Agreement, we will pay all fees and expenses incident to the performance of our obligations, including the reasonable fees of one special counsel for Citadel CEMF Investments Ltd, excluding any underwriting, broker or similar fees or commissions and other costs (except as agreed to be paid by us) of any purchaser.

Policies for Approval of Related Party Transactions

Our board of directors reviews and approves transactions with our directors, officers and holders of 5% or more of our voting securities and their affiliates, each a related party. Prior to this offering, the material facts as to the related party's relationship or interest in the transaction are disclosed to our board of directors prior to the consideration of such transaction, and the transaction is not considered approved by our board of directors unless a majority of the directors who are not interested in the transaction approve the transaction. Further, when stockholders are entitled to vote on a transaction with a related party, the material facts of the related party's relationship or interest in the transaction are disclosed to our stockholders, who must approve the transaction in good faith.

Item 14. Principal Accounting Accountant Fees and Services.

We incurred the following fees from Ernst & Young LLP for the audit of the consolidated financial statements and for other services related to the years ended December 31, 2023 and December 31, 2022. The following table summarizes the fees for Ernst & Young LLP services to the Company for the last two fiscal years.

Fee Category	Fiscal Year	Fiscal Year
	2023 (\$)	2022 (\$)
Audit Fees (1)	1,341,206	191,007
Audit-Related Fees	-	-
Tax Fees (2)	14,060	13,390
All Other Fees (3)	3,600	3,500
Total Fees	1,358,866	207,897

(1) "Audit fees" consist of fees for the audit of our annual financial statements, review of the interim financial statements included in our quarterly reports on Form 10-Q, registration statements on Form S-4, registration statements on Form S-3, registration statements on Form S-1 and other professional services provided in connection with financings and other regulatory filings.

(2) "Tax fees" consist of fees for professional services, including tax compliance, tax advice and tax planning.

(3) "All other fees" consist of fees paid to access Ernst & Young LLP publications and on-line subscriptions/content.

The information required by this Item 14 will be included in our Definitive Proxy Statement Audit Committee Pre-approval Policy and Procedures

Our audit committee has adopted policies and procedures relating to the approval of all audit and non-audit services that are to be filed with performed by our independent registered public accounting firm. This policy provides that we will not engage our independent registered public accounting firm to render audit or non-audit services unless the SEC with respect service is specifically approved in advance by our audit committee or the engagement is entered into pursuant to the pre-approval procedure described below.

From time to time, our 2023 Annual Meeting audit committee may pre-approve specified types of Stockholders services that are expected to be provided to us independent registered public accounting firm during the next 12 months. Any such pre-approval details the particular service or type of services to be provided and is incorporated herein by reference, also generally subject to a maximum dollar amount.

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PART IV

Item 15. Exhibits, Exhibit and Financial Statement Schedules.

- (1) For a list of the financial statements included herein, see the Index to the Consolidated Financial Statements

The following documents are included in Item 8 on pages F-1 through F-29 attached hereto and are filed as part page 109 of this Annual Report.

[Report of an Independent Registered Public Accounting Firm \(PCAOB ID: 49\)](#)

[Consolidated financial statements As of December 31, 2022 and 2021](#)

[Consolidated balance sheets](#)

[Consolidated statements of operations](#)

[Consolidated statements of comprehensive loss](#)

[Consolidated statements of stockholders' equity](#)

[Consolidated statements of cash flows](#)

[Notes to consolidated financial statements](#)

10-K, incorporated into this Item by reference.

- (2) Financial Statement Schedules:

All financial statement schedules have been omitted because they are not applicable, either not required or not applicable or the information required is shown included in the Consolidated Financial Statements consolidated financial statements or the Notes thereto set forth below beginning on page F-1 notes thereto.

(3) The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

		Incorporated by Reference			
Exhibit	Description	Form	No.	Exhibit	Date
	Restated Certificate of Incorporation of Frequency Therapeutics, Inc.	8-K	00	3	1/07
	Amended and Restated Executive Employment Agreement, dated as of September 20, 2019, between David L. Lucchino and Frequency Therapeutics, Inc.	8-K	00	3	9/12
	Bylaws of Frequency Therapeutics, Inc.		06	2	
	Form of Specimen Common Stock Certificate	S-1	33	4	9/13
	Second Amended and Restated Investors' Rights Agreement, dated as of July 17, 2019	1	3	2	6/23
	2019 Employee Stock Purchase Plan		23	1	
	Indenture of Lease, effective as of January 7, 2020, between HCP/KING 75 Hayden LLC and Frequency Therapeutics, Inc.	K	3906	3	2/20

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10.6	Second Amended and Restated Executive Employment Agreement, dated as of September 20, 2019, between David L. Lucchino and Frequency Therapeutics, Inc.	S-1/A	333-2336	10.7	9/23/19
10.7	Exclusive Patent License Agreement, dated as of December 13, 2016, as amended, between Massachusetts Institute of Technology and Frequency Therapeutics, Inc.	10-K	333-2336	10.7	3/15/22
10.8	Non-Exclusive Patent License Agreement, dated as of February 7, 2019, between Massachusetts Eye and Ear Infirmary and Frequency Therapeutics, Inc.	S-1	333-2336	10.1	9/6/19
10.9	License and Collaboration Agreement, dated as of July 16, 2019, between Astellas Pharma, Inc. and Frequency Therapeutics, Inc.	S-1	333-2336	10.1	9/6/19
10.10	2019 Employee Stock Purchase Plan	S-1/A	333-2336	10.1	9/23/19
10.11	Indenture of Lease, effective as of January 7, 2020, between HCP/KING 75 Hayden LLC and Frequency Therapeutics, Inc.	K	001-3906	10.1	3/26/20

90 Exhibits:

	Description	1	00	4.	3/	
4.	n of	0-	1-	3	2	
3	Frequency	K	39	6/		
	y.		06	2		
	Therapeut		2	0		
	ics, Inc.					
	Securities					
1	2014	S-	33	1	9/	
0.	Stock	1	3-	0.	6/	
1	Incentive		23	1	1	
#	Plan as		36	9		
	amended		52			
	and form					
	of option					
	agreements					
	thereunder					
	r					
1	2019	S-	33	1	9/	
0.	Incentive	1/	3-	0.	2	
2	Award	A	23	2	3/	
#	Plan and		36	1		
	form of		52	9		
	award					
	agreements					
	thereunder					
	r					
1	Non-	S-	33	1	9/	
0.	Employee	1/	3-	0.	2	
3	Director	A	23	3	3/	
#	Compensation		36	1		
	Program		52	9		
1	Form of	S-	33	1	9/	
0.	Indemnification	1/	3-	0.	2	
4	Agreement	A	23	5	3/	
	t for		36	1		
	Directors		52	9		
	and					
	Officers					
10.1	Sublease	8-K	001-	10.1	7/12	
2	Agreement, dated		3906		/22	
	July 8, 2022, by and		2			
	between Frequency					
	Therapeutics, Inc.					
	and SalioGen					
	Therapeutics, Inc.					
10.1	Registration Rights	8-K	001-	10.2	7/21	
3	Agreement, dated		3906		/20	
	July 17, 2020, by		2			
	and among					
	Frequency					
	Therapeutics, Inc.					
	and the Investors					
	named therein.					
10.1	Loan and Security	8-K	001-	10.1	12/1	
4	Agreement, dated		3906		5/20	
	December 11, 2020,		2			
	by and between					
	Frequency					
	Therapeutics, Inc.					
	and Silicon Valley					
	Bank.					
10.1	Separation	8-K	001-	10.1	3/31	
5#	Agreement, dated		3906		/22	
	as of March 31,		2			
	2022, by and					
	between Frequency					
	Therapeutics, Inc.					
	and Peter P.					
	Pfreundschuh					
10.1	Employment	10-	001-	10.1	3/26	
6#	Agreement, effective	K	3906	6	/21	
	February 3, 2020, by		2			
	and between					
	Frequency					
	Therapeutics, Inc.					
	and Wendy S.					
	Arnold.					
21.1	Subsidiaries of					*
	Frequency					
	Therapeutics, Inc.					
23.1	Consent of RSM					*
	US, LLP.					
	Independent					
	Registered Public					
	Accounting Firm					

31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	*
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a).	*

Exhibit Number	Description
2.1+	Agreement and Plan of Merger and Reorganization, dated as of July 14, 2023, by and among the registrant, Frequency Merger Sub, Inc. and the entity formerly known as Korro Bio, Inc. (incorporated by reference to Exhibit 2.1 to the registrant's Current Report on Form 8-K filed on July 14, 2023).
3.1	Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed on October 7, 2019).
3.2	Certificate of Amendment to Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed on November 6, 2023).
3.3	Certificate of Amendment to Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.2 to the registrant's Current Report on Form 8-K filed on November 6, 2023).
3.4	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed on September 23, 2020).
4.1	Description of Securities
10.1#	Korro Bio, Inc. 2023 Stock Option and Incentive Plan, and form of award agreements thereunder (incorporated by reference to Exhibit 10.1 to the registrant's Registration Statement on Form S-1/A filed December 20, 2023).
10.2#	Korro Bio, Inc. 2023 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.2 to the registrant's Registration Statement on Form S-1/A filed December 20, 2023).
10.3#	Korro Bio, Inc. 2019 Stock Incentive Plan, and form of award agreements thereunder (incorporated by reference to Exhibit 10.8 to the registrant's Current Report on Form 8-K filed on November 6, 2023).
10.4#	Korro Bio, Inc. Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.11 to the Form 8-K, filed November 6, 2023).
10.5#	Frequency Therapeutics, Inc. 2014 Stock Incentive Plan, as amended, and form of option agreements thereunder (incorporated by reference to Exhibit 10.1 to the registrant's Registration Statement on Form S-1 (333-233652) filed on September 6, 2019).
10.6#	Frequency Therapeutics, Inc. 2019 Incentive Award Plan and form of award agreements thereunder (incorporated by reference to Exhibit 10.2 to the registrant's Registration Statement on Form S-1/A (333-233652) filed on September 23, 2019).
10.7#	Frequency Therapeutics, Inc. 2019 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.13 to the registrant's Registration Statement on Form S-1/A (333-233652) filed on September 23, 2019).
10.8#	Korro Bio, Inc. Senior Executive Cash Incentive Bonus Plan (incorporated by reference to Exhibit 10.12 to the Form 8-K, filed November 6, 2023).
10.9#	Employment Agreement, dated as of November 10, 2023, by and between Korro Bio, Inc. and Ram Aiyar, Ph.D. (incorporated by reference to Exhibit 10.1 to the Form 8-K filed November 14, 2023).

- 10.10# [Employment Agreement, dated November 8, 2023, by and between Korro Bio, Inc. and Vineet Agarwal \(incorporated by reference to Exhibit 10.2 to the Form 8-K filed November 14, 2023\).](#)
- 10.11# [Employment Agreement, dated November 8, 2023, by and between Korro Bio, Inc. and Shelby Walker \(incorporated by reference to Exhibit 10.11 to the registrant's Registration Statement on Form S-1/A filed December 20, 2023\).](#)
- 10.12# [Employment Agreement, dated November 8, 2023, by and between Korro Bio, Inc. and Steve Colletti \(incorporated by reference to Exhibit 10.12 to the registrant's Registration Statement on Form S-1/A filed December 20, 2023\).](#)
- 10.13# [Employment Agreement, dated November 9, 2023, by and between Korro Bio, Inc. and Todd Chappell \(incorporated by reference to Exhibit 10.13 to the registrant's Registration Statement on Form S-1/A filed December 20, 2023\).](#)
- 10.14# [Form of Indemnification Agreement for Officers of Korro Bio, Inc. \(incorporated by reference to Exhibit 10.6 to the Form 8-K filed November 6, 2023\).](#)
- 10.15# [Form of Indemnification Agreement for Directors of Korro Bio, Inc. \(incorporated by reference to Exhibit 10.7 to the Form 8-K filed November 6, 2023\).](#)

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- 10.16 [Third Amended and Restated Investors' Rights Agreement of Korro Bio, Inc., dated November 8, 2021 \(incorporated by reference to Exhibit 10.27 to Form S-4/A filed September 28, 2023\).](#)
- 10.17 [Form of Lock-Up Agreement \(incorporated by reference to Exhibit 10.3 to the Form 8-K filed November 6, 2023\).](#)
- 10.18 [Contingent Value Rights Agreement dated November 3, 2023 \(incorporated by reference to Exhibit 10.4 to the Form 8-K filed November 6, 2023\).](#)
- 10.19 [Lease Agreement, by and between Korro Bio, Inc. and ARE-MA Region No. 59, LLC, dated August 10, 2020, as amended on March 2, 2021 \(incorporated by reference to Exhibit 10.21 to the Form S-4 filed September 28, 2023\).](#)
- 10.20 [Second Amendment to Lease Agreement, by and between Korro Bio, Inc. and ARE-MA Region No. 59, LLC, dated August 31, 2022.](#)
- 10.21 [Third Amendment to Lease Agreement, by and between Korro Bio, Inc. and ARE-MA Region No. 59, LLC, dated October 20, 2023.](#)
- 10.22 [Indenture of Lease, effective as of January 7, 2020 between HCP/KING 75 Hayden LLC and Frequency Therapeutics \(incorporated by reference to Exhibit 10.13 to the registrant's Annual Report on Form 10-K filed on March 26, 2020\).](#)
- 10.23 [Sublease Agreement, dated July 8, 2022, by and between Frequency Therapeutics, Inc., and SalioGen Therapeutics, Inc. \(incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed on July 12, 2022\).](#)
- 10.24 [Subscription Agreement, dated as of July 14, 2023 \(incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed on November 6, 2023\).](#)
- 10.25 [Registration Rights Agreement, dated as of July 14, 2023 \(incorporated by reference to Exhibit 10.2 to the registrant's Current Report on Form 8-K filed on November 6, 2023\).](#)
- 10.26 [Warrant Agreement dated January 22, 2021 \(incorporated by reference to Exhibit 10.13 to the Form 8-K, filed November 6, 2023\).](#)
- 21.1 [List of Subsidiaries.](#)
- 23.1 [Consent of Ernst & Young LLP.](#)
- 24.1 [Power of Attorney \(included on the signature page attached hereto\).](#)
- 31.1 [Certification of Principal Executive Officer Pursuant to Rules 13a-14\(a\) and 15d-14\(a\) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.](#)
- 31.2 [Certification of Principal Financial Officer Pursuant to Rules 13a-14\(a\) and 15d-14\(a\) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.](#)
- 32.1 32.1# [Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.](#)
- 32.2 [Certification of and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.](#)
- 97.1# [Korro Bio, Inc. Compensation Recovery Policy.](#)

101.INS Inline XBRL Instance Document

101.SCH Inline XBRL Taxonomy Extension Schema Document

101.CAL Inline XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF Inline XBRL Extension Definition Linkbase Document

101.LAB Inline XBRL Taxonomy Extension Label Linkbase Document

101.PRE Inline XBRL Taxonomy Extension Presentation Linkbase Document

104 The cover page for Cover Page Interactive Data File (embedded within the Company's Annual Report on Form 10-K has been formatted in Inline XBRL and contained in Exhibit 101.

* Filed herewith # Indicates a management contract or any compensatory plan, contract or arrangement.

** Furnished herewith

*** Submitted electronically herewith

† Portions of this exhibit + Schedules and exhibits have been omitted pursuant to Item 601 601(b)(2) of Regulation S-K promulgated S-K. We agree to furnish supplement a copy of any omitted schedule or exhibit to the SEC upon request.

¥ These certifications will not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section. Such certification will be deemed to be incorporated by reference into any filing under the Securities Act because or the information is not material and would be competitively harmful if published.

disclosed.
A management contract or compensatory plan or arrangement required Exchange Act except to be filed as an exhibit pursuant to Item 15(a)(3) of Form 10-K. the ex specifically incorporated by reference into such filing.

Item 16. Form 10-K Summary

None.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant registrant has duly caused this Report report to be signed on its behalf by the undersigned, thereunto duly authorized.

FREQUENCY THERAPEUTICS, INC. Korro Bio, Inc.

Date: March 10, 2023 March 26, 2024
By: /s/ David L. Lucchino Ram Aiyar
David L. Lucchino Ram Aiyar
President and Chief Executive Officer and Director (Principal Executive Officer)

POWER OF ATTORNEY

Each KNOW ALL PERSONS BY THESE PRESENTS, that each person whose individual signature appears below hereby authorizes constitutes and appoints L. Lucchino Ram Aiyar and Richard Mitrano, Vineet Agarwal, and each of them, with full power of substitution and resubstitution and full power to act without the other, or her true and lawful attorney-in-fact attorneys-in-fact and agent to act agents, each with the full power of substitution, for him or her and in his or her name, place or s in any and stead and all capacities, to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file sign any and all amendments to this annual report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing re and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all t said attorneys-in-fact and agents, or any of them their, his or their or his her substitute or substitutes, may lawfully do or cause to be done by virtue thereof. hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report report has been signed below by the following persons on beh the Registrant registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Ram Aiyar Ram Aiyar	President, Chief Executive Officer and Director Principal Executive Officer	March 26, 2024
/s/Vineet Agarwal Vineet Agarwal	Chief Financial Officer Principal Financial Officer and Principal Accounting Officer	March 26, 2024
/s/ Ali Behbahani Ali Behbahani	Director	March 26, 2024
/s/ Nesson Bermingham Nesson Bermingham	Director	March 26, 2024
/s/ Jean-Francois Formela Jean-Francois Formela	Director	March 26, 2024

/s/ David L. Lucchino	President, Chief Executive Officer and Director (Principal Executive Officer)	March 10, 2023 26, 2024
David L. Lucchino		
/s/ Richard Mitrano Rachel Meyers	Vice President, Finance and Operations (Principal Financial and Accounting Officer) Director	March 10, 2023 26, 2024
Richard Mitrano Rachel Meyers		
/s/ Timothy J. Barberich	Vice Chairperson and Director	March 10, 2023
Timothy J. Barberich		
/s/ Cynthia L. Feldmann Pearson	Director	March 10, 2023 26, 2024
Cynthia L. Feldmann Timothy Pearson		
/s/ Michael Huang	Director	March 10, 2023
Michael Huang		
/s/ Robert S. Langer	Director	March 10, 2023
Robert S. Langer, Sc.D.		
/s/ Joel S. Marcus	Director	March 10, 2023
Joel S. Marcus		

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Report of Independent Registered Public Accounting Firm	
To the Stockholders and the Board of Directors of Frequency Therapeutics, Inc.	
Opinion on the Financial Statements	
We have audited the accompanying consolidated balance sheets of Frequency Therapeutics, Inc. and its subsidiaries (the Company) as of December 31, 2022 and 21 the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for the years then ended, and the related notes to the consolidated financial statements (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial pos of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended, in conformity with accounting princip generally accepted in the United States of America.	
Basis for Opinion	
These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements be on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.	
We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial report but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinia Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial stateme	

Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

We have served as the Company's auditor since 2017.

/s/ RSM US LLP

Boston, Massachusetts

March 10, 2023

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Frequency Therapeutics, Inc.

Consolidated Balance Sheets

(in thousands, except share and per share amounts)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 51,954	\$ 79,000
Short-term marketable securities	31,143	51,000
Prepaid expenses and other current assets	4,396	4,000
Total current assets	87,493	134,000
Long-term marketable securities	—	11,000
Property and equipment, net	2,739	5,000
Right of use assets	28,980	31,000
Restricted cash	1,699	1,000
Other long-term assets	327	—
Total assets	\$ 121,238	\$ 185,000
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 3,114	\$ 2,000
Accrued expenses	5,891	6,000
Lease liabilities, current portion	2,021	1,000
Term loan, current portion	10,000	—
Total current liabilities	21,026	11,000
Lease liabilities, net of current portion	26,761	28,000
Term loan, net of current portion	4,167	14,000
Other long-term liabilities	89	—
Total liabilities	52,043	54,000
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized, no shares issued or outstanding at December 31, 2022 and December 31, 2021, respectively	—	—
Common stock, \$0.001 par value; 200,000,000 shares authorized, 35,262,083 and 34,611,213 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	35	—
Additional paid-in capital	331,023	310,000
Accumulated other comprehensive loss	(198)	—
Accumulated deficit	(261,665)	(180,000)
Total stockholders' equity	69,195	130,000
Total liabilities and stockholders' equity	\$ 121,238	\$ 185,000

See accompanying notes.

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Frequency Therapeutics, Inc.

Consolidated Statements of Operations

(in thousands, except share and per share amounts)

	Year Ended	
	December 31,	
	2022	2021
Revenue	\$ -	\$ 14,000
Operating expenses:		
Research and development	49,418	60,900
General and administrative	33,584	37,100
Total operating expenses	83,002	98,000
Loss from operations	(83,002)	(84,000)
Interest income	1,327	300
Interest expense	(961)	(700)
Realized gain (loss) on investments	3	(200)
Foreign exchange (loss) gain	(5)	0
Other income (expense), net	1,056	(200)
Loss before income taxes	(81,582)	(84,600)
Tax benefit (provision)	2	(200)
Net loss	\$ (81,580)	\$ (84,600)
Net loss per share-basic and diluted	\$ (2.33)	\$ (2.40)
Weighted-average shares of common stock outstanding-basic and diluted	35,075,924	34,351,200

See accompanying notes.

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Frequency Therapeutics, Inc.
Consolidated Statements of Comprehensive Loss
(in thousands, except share and per share amounts)

	Year Ended	
	December 31,	
	2022	2021
Net loss	\$ (81,580)	\$ (84,600)
Other comprehensive loss:		
Unrealized loss on marketable securities	(136)	(600)
Total comprehensive loss	(136)	(600)
Comprehensive loss	\$ (81,716)	\$ (84,700)

See accompanying notes.

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Frequency Therapeutics, Inc.
Consolidated Statement of Stockholders' Equity
(in thousands, except share and per share amounts)

	Common shares issued	Common par value	Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
Balance, December 31, 2020	33,964,000	\$ 34	\$ 287,829	\$ 27	\$ (95,399)	\$ 227,501
Stock-based compensation expense	—	—	21,750	—	—	21,750
Purchases under Employee Stock Purchase Plan	7,064	—	60	—	—	7,124
Issuance of common stock upon exercise of stock options	642,314	1	1,297	—	—	1,302
Forfeiture of restricted stock	(2,165)	—	—	—	—	(2,165)
Other comprehensive loss	—	—	—	(89)	—	(89)
Net loss	—	—	—	—	(84,686)	(84,686)
Balance, December 31, 2021	34,611,213	\$ 35	\$ 310,936	\$ (62)	\$ (180,085)	\$ 130,824
Stock-based compensation expense	—	—	19,831	—	—	19,831

Purchases under Employee Stock Purchase Plan	76,606	—	196	—	—
Issuance of common stock upon exercise of stock options	10,047	—	11	—	—
Issuance of common stock under equity offering	12,767	—	50	—	—
Issuance of common stock pursuant to restricted stock units	551,450	—	(1)	—	—
Other comprehensive loss	—	—	—	(136)	—
Net loss	—	—	—	—	(81,580)
Balance, December 31, 2022	35,262,083	\$ 35	\$ 331,023	\$ (198)	\$ (261,665)

See accompanying notes

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Frequency Therapeutics, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (81,580)	\$ (84,661)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	19,831	21,741
Depreciation expense	2,766	2,741
Non-cash lease expense	2,370	1,041
Non-cash interest expense	396	341
Loss on disposal of assets	—	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	681	(1,041)
Accounts payable	(677)	(2,241)
Deferred revenue	—	(14,041)
Lease liabilities	(1,816)	(3,041)
Accrued expenses	(208)	(3,041)
Net cash used in operating activities	(58,237)	(76,041)
Cash flows from investing activities:		
Sale of property and equipment	17	—
Purchase of property and equipment	—	(2,941)
Purchase of marketable securities	(54,222)	(92,441)
Redemption of marketable securities	85,338	29,241
Net cash provided by (used in) investing activities	31,133	(66,141)
Cash flows from financing activities:		
Proceeds from issuance of common stock	60	1,241
Proceeds from Employee Stock Purchase Plan	196	—
Repayment of term loan	(833)	—
Net cash (used in) provided by financing activities	(577)	1,341
Net decrease in cash, cash equivalents, and restricted cash	(27,681)	(140,841)
Cash, cash equivalents, and restricted cash at beginning of period	81,334	222,141
Cash, cash equivalents, and restricted cash at end of period	<u>\$ 53,653</u>	<u>\$ 81,300</u>
Supplemental disclosures:		
Cash paid for interest	\$ 914	\$ 741

See accompanying notes

Frequency Therapeutics, Inc.

Notes to Consolidated Financial Statements

(Amounts in thousands, except share and per share amounts)

1. Organization

Frequency Therapeutics, Inc., together with its wholly owned subsidiaries, Frequency Therapeutics, PTY, LTD, Frequency Therapeutics Securities Corporation, Frequency Therapeutics Japan KK (Frequency Japan) (the Company), headquartered in Lexington, Massachusetts, was incorporated in November 2014 as a Delaware corporation. Frequency Japan was closed down in February 2021. The Company is a preclinical-stage regenerative medicine company focused on developing therapies to activate a person's innate regenerative potential to restore function.

Liquidity and capital resources

The Company has funded its operations primarily with proceeds from private and public securities financings, a term loan, and amounts received under a collaboration agreement. The Company has incurred recurring losses since its inception. In addition, as of December 31, 2022, the Company had an accumulated deficit of \$261,665. The Company expects to continue to generate operating losses for the foreseeable future. The future viability of the Company is dependent on its ability to raise additional capital to finance its operations. The Company's inability to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies. There can be no assurances that additional funding will be available on terms acceptable to the Company, or at all. The Company believes that existing resources will be sufficient to fund planned operations for at least 12 months from the date the financial statements were available to be issued.

2. Summary of significant accounting policies

Basis 163

Exhi

DESCRIPTION OF SECURITIES

General

The following description summarizes some of the presentation

The accompanying consolidated financial statements have been prepared in accordance with the terms of our restated certificate of incorporation, as amended, or the Charter, our amended and restated bylaws, or the Bylaws, and of the General Corporation Law of Delaware, or the DGCL. This description is summarized from, and qualified in accordance with accounting standards set forth in its entirety by the Financial Accounting Standards Board (FASB). The FASB sets generally accepted accounting principles (GAAP) that the Company follows to ensure its financial condition, results of operations, and cash flows are consistently reported. References to GAAP issued by the FASB in these notes reference to, the consolidated financial statements are our Charter and Bylaws, each of which has been filed as an Exhibit to our Annual Report on Form 10-K, as well as the FASB Accounting Standards Codification (ASC).

Principles of consolidation

The consolidated financial statements include the accounts of Frequency Therapeutics, Inc. and its wholly owned subsidiaries Frequency Therapeutics Securities Corporation, Frequency Therapeutics PTY, LTD and Frequency Japan through the date of its dissolution. All intercompany transactions and balances have been eliminated.

Use of estimates

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts in the consolidated financial statements.

Capital stock

Our authorized capital stock consists of 200,000,000 shares. At the date of the consolidated financial statements and reported amounts of expenses during the reporting period. On an ongoing basis, the Company's management evaluates its estimates and assumptions which include but are not limited to management's judgments of accrued expenses, revenue recognition, fair value of common stock, valuation of preferred stock, and share-based awards, preferred stock, par value \$0.001 per share, and 10,000,000 shares of share-based awards, preferred stock, par value \$0.001 per share.

Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Subject to the

supermajority votes for some matters, other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by stockholders present **value** or represented and voting on such matters. The Charter and Bylaws also provide that our directors may be removed only for cause and on the affirmative vote of **lease** the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon. In addition, the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon is required to amend or repeal, or to adopt a provision inconsistent with, several of the provisions of the Charter. See below under "Anti-takeover effects of Delaware law and Charter and Bylaws-Amendment of c provisions." Holders of common stock are entitled to receive proportionately any dividends as may be declared by its board of directors, subject to any preferential dividends of any series of preferred stock that we may designate and issue in the future.

In the event of our liquidation or dissolution, the holders of our common stock are entitled to receive proportionately our net assets available for distribution to stockholders after the payment of all debts and other liabilities and income taxes. Actual results could differ from those estimates.

Comprehensive loss

Components of comprehensive loss, including net loss, are reported in **subject to the financial statements in the period in which they are recognized. Other comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net loss and o comprehensive loss are reported net prior rights of any related tax effect outstanding preferred stock. Holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of our common stock are subject to, arrive at comprehensive loss. Comprehensive l includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders which for the y ended December 31, 2022 and 2021 consist of unrealized loss on marketable securities.**

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Segment information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision-maker in deciding how to allocate resources and assess performance. The Company and the Company's chief operating decision-maker, the Company's chief executive officer, view the Company's operations and manage its business as a single operating segment, which is in the business of developing therapeutics to activate a person's innate regenerative potential to restore function.

Foreign currency

All periods presented are reported in US dollars. The functional currency for entities outside the United States is the US dollar. Realized and unrealized gains and losses from foreign currency transactions are reflected in the consolidated statements of operations as other expense. During the years ended December 31, 2022 and 2021 the Company recorded \$5 of foreign currency exchange loss and \$16 of foreign currency exchange gain, respectively.

Cash and cash equivalents

The Company considers all highly liquid investments with an original maturity of six months or less at acquisition to be cash equivalents which are stated at fair market value. Cash and cash equivalents at December 31, 2022 and 2021 consists entirely of cash and money market funds.

Restricted cash

The Company has \$1,699 of restricted cash as of December 31, 2022 and December 31, 2021, which represents a security deposit on the Company's Lexington, Massachusetts facility.

Marketable securities

Marketable securities represent holdings of available-for-sale marketable debt securities in accordance with the Company's investment policy. Short-term marketable securities mature within one year from the balance sheet date while long-term marketable securities mature after one year. Investments in marketable securities are recorded at fair value, with any unrealized gains and losses reported within accumulated other comprehensive income as a separate component of stockholders' equity until realized or until a determination is made that an other-than-temporary decline in market value has occurred. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are reflected as a component of other expense. Interest on securities is determined based on the specific identification method and reflected as interest income. Any realized gains or losses on the sale of investment are reflected as realized gain (loss) on investments.

Concentration of credit risk and off-balance sheet risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents and marketable securities. The Company maintains its cash, cash equivalents, and restricted cash at several accredited financial institutions, in amounts that exceed federally insured limits. Marketable securities consist of short term and long term investments. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which its money market accounts are maintained.

The Company has no significant off-balance sheet arrangements such as foreign exchange contracts, option contracts, or other foreign hedging arrangements.

Significant suppliers

The Company is dependent on third-party manufacturers to supply products for research and development activities of its programs, including preclinical and clinical testing. In particular, the Company relies and expects to continue to rely on a single manufacturer of its product candidates for use in clinical trials. The Company would be adversely affected by, a significant interruption the rights of the stockholders of shares of any series of our preferred stock that we may designate and issue in the sale of product for use in clinical programs.

Fair value measurements

Preferred Stock

Fair value is defined as the price that would be received upon sale of an asset or paid to transfer a liability between market participants at measurement dates. Topic 820, *Fair Value Measurement* (ASC 820), establishes a three-level

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valuation hierarchy for instruments measured at fair value. The hierarchy is based on the transparency of inputs to the valuation of an asset or liability as of the measurement date. The hierarchy defines three levels of valuation inputs, of which the first two are considered observable and the last is considered unobservable:

- Level 1 Quoted prices in active markets for identical assets or liabilities.
 - Level 2 Inputs other than quoted prices included within Level 1 that are either directly or indirectly observable, such as quoted market prices, interest rates and yield curves.
 - Level 3 Unobservable inputs developed using estimates or assumptions developed by the Company, which reflect those that a market participant would use pricing the asset or liability.
- To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires management judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.
- The carrying amounts reflected in the consolidated balance sheet for prepaid expenses and other current assets, accounts payable, accrued expenses, other liabilities, and term loan are shown at their historical values which approximate their fair values.

Property and equipment, net

Property and equipment consist of lab equipment, furniture and office equipment and software recorded at cost. These amounts are depreciated using the straight line method over the estimated useful lives of the assets as follows:

	Estimated useful life
Lab equipment	5
Software	3
Furniture and office equipment	5

Upon retirement or sale, the cost of the assets disposed of and the related accumulated depreciation are eliminated from the balance sheet and related gains or losses are reflected in the consolidated statements of operations.

Impairment of long-lived assets

The Company continually evaluates long-lived assets for potential impairment when events or changes in circumstances indicate the carrying value of the asset may not be recoverable. Recoverability is measured by comparing the book values of the assets to the expected future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book values of the assets exceed their fair value. The Company did not recognize any impairment losses for the years ended December 31, 2022 and 2021.

Research and development costs and accruals

Research and development expenses include salaries and benefits, materials and supplies, preclinical and clinical trial expenses, stock-based compensation expense, depreciation of equipment, contract services and other outside expenses. The Company has entered into various research and development-related contracts with research institutions, contract research organizations, contract manufacturers and other companies. These agreements are generally cancelable, and related payments recorded as research and development expenses as incurred. Costs of certain development activities, such as manufacturing, preclinical and clinical trial expenses, are recognized based on an evaluation of the progress to completion of specific tasks. Payments for these activities are based on the terms of the individual arrangements. Under the terms of the individual arrangements, our board of directors is authorized to direct us to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption rights and liquidation preferences, of each series of our preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine our rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock.

Anti-takeover effects of Delaware law and Charter and Bylaws

Some provisions of Delaware law, Charter and Bylaws could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions that provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with its board of directors.

Undesignated preferred stock

The ability of our board of directors, without action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of us. These and other provisions may differ and have the effect of deferring hostile takeovers or delaying changes in control or management of us.

Stockholder meetings

The Bylaws provide that a special meeting of stockholders may be called only by our chairman of the board of directors, chief executive officer or president (in the absence of a chief executive officer), or by a resolution adopted by a majority of our board of directors.

Requirements for advance notification of stockholder nominations and proposals

The Bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of stockholder action by written consent

The Charter eliminates the right of stockholders to act by written consent without a meeting.

Staggered board

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by its stockholders. This system of electing and removing directors may tend to discourage a third-party from making a tender offer or otherwise attempting to obtain control because it generally makes it more difficult for stockholders to replace a majority of the pattern directors.

Removal of costs incurred, directors

The Charter provides that no member of our board of directors may be removed from office by our stockholders except for cause and, as reflected in addition to the other vote required by law, upon the approval of the holders of at least two-thirds in voting power of the outstanding shares of our common stock entitled to vote in the consolidated financial statements as prepaid or accrued research and development costs. Nonrefundable advance payments election of directors.

Stockholders not entitled to cumulative voting

The Charter does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for goods or services election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

Delaware anti-takeover statute

We are subject to Section 203 of the DGCL, which prohibits persons deemed to be received "interested stockholders" from engaging in a "business combination" with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "inter

stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15 more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors

Choice of forum

The Charter provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will, to the fullest extent permitted by applicable law, be the sole and exclusive forum for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim for breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against arising pursuant to any provision of the DGCL or the Charter or Bylaws; (4) any action to interpret, apply, enforce or determine the validity of the Charter or Bylaws; or any action asserting a claim governed by the internal affairs doctrine. Under the Charter, this exclusive forum provision does not apply to claims which are vested in the future exclusive jurisdiction of a court or forum other than the Court of Chancery of the State of Delaware, or for use in research and development activities are deferred. The capitalized amounts are expensed as which the related goods are delivered. Court of Chancery of the State of Delaware does not have subject matter jurisdiction. For instance, the provision would not apply to actions arising under federal securities laws, including suits brought to enforce any liability or duty created by Exchange Act or the services are performed. Costs incurred rules and regulations thereunder. The Charter also provides that any person or entity purchasing or otherwise acquiring any interest in obtaining technology licenses are charged shares of its capital stock will be deemed to research have notice of and development expense as acquired in-process research and development to have consented to this choice of forum provision. The Charter further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. It is possible that a court of law could rule that the choice of forum provision contained in the Charter is inapplicable or unenforceable if it is challenged in a proceeding or otherwise.

Amendment of charter provisions

The amendment of any of the technology licensed has not reached technological feasibility and has no alternative future use.

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Leases

The Company accounts for leases under ASC 842, Leases. The Company determines if an arrangement is, or contains, a lease at inception and, if so, records a right-of-use (ROU) asset and a lease liability on the consolidated balance sheet for any lease with a term longer than 12 months.

ROU assets represent the Company's right to use an underlying asset above provisions, except for the lease term provision making it possible for our board of directors to issue preferred stock and lease liabilities represent the Company's obligation provision prohibiting cumulative voting, would require approval by holders of at least two-thirds in voting power of the outstanding shares of stock entitled to make lease payments arising vote thereon. The provisions of Delaware law, the Charter and Bylaws could have the effect of discouraging others from the lease. ROU assets attempting hostile takeovers and liabilities are recognized at the lease commencement based on the present value of lease payments to be made over the lease term. The ROU asset also includes any lease payments made at or before the lease commencement date and excludes lease incentives received. As the Company's lease does not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments. The lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Operating lease expense is recognized on a straight-line basis over the lease term. The Company has elected to not apply the recognition requirements of ASC 842 for short-term leases, which is defined as a lease that, at the lease commencement date, has a lease term of 12 months or less and does not include an option to purchase the underlying asset that the Company is reasonably certain to exercise.

For real estate lease agreements entered into or modified after the adoption of ASC 842 that include lease and non-lease components, the Company has elected to account for the lease and non-lease components, such as common area maintenance charges, as a single lease component.

Collaborative arrangements

The Company analyzes its collaborative arrangements to assess whether consequence, they are within the scope of ASC 808, Collaborative Arrangements (ASC 808) to determine whether such arrangements involve joint operating activities performed by parties that are both active participants may also inhibit temporary fluctuations in the activities and exposed to significant risks and rewards dependent on market price of its common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the commercial success effect of such activities. This assessment is performed throughout the life of the arrangement based on preventing changes in the responsibilities composition of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 directed and management. It is possible that contain multiple elements, the Company first determines which elements of the collaboration are deemed these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be within the scope in their best interests.

SECOND AMENDMENT TO LEASE

THIS SECOND AMENDMENT TO LEASE (this "Second Amendment") is made as of ASC 808 August 2022, by and those that are more reflective of between ARE-IV REGION NO. 59, LLC, a vendor-customer relationship (e.g. Delaware limited liability company ("Landlord"), and KORRO BIO, INC., a licensing arrangement) where Delaware corporation ("Tenant").

RECITALS

A. Landlord and Tenant are now parties to that certain Lease Agreement dated as of August 10, 2020, as amended by that certain First Amendment to Lease dated as of March 2, 2021 (as amended, the contracted party has obtained goods or services "Lease"). Pursuant to the Lease, Tenant leases certain premises commonly known as Suite 6-401, containing approximately 12,165 rentable square feet (the "Original Premises") in that are an output of the Company's ordinary activities in exchange for a consideration and therefore within the scope of ASC 606, *Revenue from Contracts with Customers* (ASC 606). For those elements of the arrangement that are accounted for pursuant to ASC 606, including those to which ASC 606 is applied by analogy, the Company applies the five step model certain building located at Building 600/700 at One Kendall Square, Cambridge, Massachusetts (the "600/700 Building"), as more particularly described in the Company's revenue recognition policy. For elements Lease. Capitalized terms used herein without definition shall have the meanings defined for such terms in the Lease.

B. The Term of collaborative arrangements the Lease is scheduled to expire on January 31, 2024.

C. Landlord and Tenant desire, subject to the terms and conditions set forth below, to amend the Lease to, among other things, (i) accelerate the expiration date of the Term of the Lease from January 31, 2024 to December 31, 2023 (the "Second Amendment Expiration Date") and (ii) provide for Tenant's lease of certain space consisting of approximately 10,396 rentable square feet, commonly known as Suite 14-201 located in that certain building located at Building 1400 at One Kendall Square, Cambridge, Massachusetts (the "1400 Building"), as shown on Exhibit A attached to this Second Amendment (the "1400 Building Premises").

NOW, THEREFORE, in consideration of the foregoing Recitals, which are accounted incorporated herein by this reference, the mutual promises and conditions contained herein, and for pursuant to ASC 808, an appropriate other good and rational recognition method valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant hereby agree as follows:

1. **Term.** As of the 1400 Building Premises Commencement Date (as defined below), the defined term "Base Term" on page 1 of the Lease is: determined deleted in its entirety and applied consistently. Reimbursements from the counterparty that are the result of a collaborative relationship replaced with the counterparty, instead of a customer relationship, such as co-development or clinical activities, are recorded as a reduction to research and development expense as following:

"Base Term: Beginning on (i) the services are performed. Similarly, amounts that are owed to a collaboration partner related Commencement Date with respect to the co-development clinical activities are recognized as research and development expense.

The Company enters into out-licensing agreements that are within the scope of ASC 606. The terms of such out-license agreements include licenses to functional intellectual property (IP), given the functionality of the intellectual property is not expected to change substantially as a result of the licensor's ongoing activities. Such arrangements typically include payment of one or more of the following: non-refundable up-front license fees; reimbursement of certain costs; development and regular milestone payments and milestone payments based on the level of sales; and royalties on net sales of licensed products.

The Company considers the economic and regulatory characteristics of the licensed IP, research, development, manufacturing and commercialization capabilities of the licensee and the availability of the associated expertise in the general marketplace to determine if it has standalone value at the inception of the licensing arrangement which would make the license distinct. In addition, the Company considers whether the licensee can benefit from a promise for its intended purpose without the receipt of any additional good or services promised in the contract, whether the value of the license is dependent on the remaining goods and services, whether there are other vendors that could provide the remaining promise, and whether the license is separately identifiable from the remaining good and services. For licenses that are combined with other goods and services, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of progress and related revenue recognition. The measure of progress, and thereby periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the research and development and licensing agreement. Such a change could have a material impact on the amount of revenue the Company records in future periods.

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Revenue is allocated to the licensed IP on a relative standalone selling price basis and, for functional IP, is recognized at a point when the licensed IP is made available for the customer's use and benefit, which generally occurs at the inception of the arrangement. However, in cases, where the functionality of the IP is expected to substantively change as a result of activities of the Company that do not transfer additional promised goods or services, or in cases, where there is an expectation that the Company will undertake activities to change the standalone functionality of the IP and the customer is contractually or practically required to use the latest version of the IP, revenue for the license to functional IP is recognized over time.

Development and regulatory milestone fees, which are a type of variable consideration, are recognized as revenue to the extent that it is probable that a significant reversal will not occur. The Company recognizes royalty revenue and sales-based milestones at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied.

The Company has entered into a collaboration arrangement with Astellas Pharma Inc. (Astellas), as further described in Note 13, "Collaboration agreement", in the notes to consolidated financial statements.

Revenue recognition

The Company accounts for contracts with customers in accordance with ASC 606, including all amendments thereto. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as collaborative arrangements and leases. The Company's disclosure within the balance sheet

sections or elsewhere within these consolidated financial statements reflects the Company's accounting policies in compliance with this standard.

Under ASC 606, an entity recognizes revenue when or as its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To recognize revenue for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies its performance obligations. The Company's Original Premises only applies the five-step model to contracts when it is probable that the entity will collect substantially all of the consideration to which it will be entitled in exchange for the goods or services it transfers to the customer. Once a contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and identifies as a performance obligation each promise to transfer to the customer either (a) a good or service (or bundle of goods and services) that is distinct, or (b) a series of distinct goods and services that are substantially the same and have been the same pattern of transfer to the customer.

The Company assesses whether each promised good or service is distinct for the purpose of identifying the performance obligations in the contract. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services and whether such are separable from the other aspects of the contractual relationship. Promised goods and services are considered distinct provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct) and the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract. For each arrangement that results in revenues, the Company identifies all performance obligations, which may include, for example, a license to IP and know-how, research and development activities, and/or manufacturing services.

2. **1400 Building Premises.** In assessing whether a promised good or service is distinct, the Company considers factors such as the research and development capabilities of the collaboration partner (the "customer" in this type of arrangement) and the availability of the associated expertise in the general marketplace. The Company also considers the intended benefit of the contract in assessing whether a promised good or service is separately identifiable from other promises in the contract. If a promised good or service is not distinct, an entity is required to combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct. For each arrangement that results in revenues, the Company identifies all performance obligations, which may include, for example, a license to IP and know-how, research and development activities, and/or manufacturing services.

In addition to any upfront payment, if the consideration promised in a contract includes a variable amount, Original Premises, commencing on the Company estimates 1400 Building Premises Commencement Date (as defined below), Landlord leases to Tenant, and Tenant leases from Landlord, the amount 1400 Building Premises.

Delivery. The "1400 Building Premises Commencement Date" shall be the date that is 1 business day after mutual execution by the parties of the contract. The Company determines the amount of variable consideration by using the expected value method or the most likely amount method. The Company includes the estimated variable consideration in the transaction price to Lease: (i) Tenant shall accept the extent it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included 1400 Building Premises in the transaction price and any

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related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment.

If an arrangement includes development and regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. If it is probable that a significant revenue reversal will not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or of the licensee such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

For contracts that include sales-based royalties (including milestone payments based on the level of sales) promised in the exchange for licenses of intellectual property, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes royalty revenue and sales-based milestone payments at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied. In determining the transaction price, the Company adjusts the promised amount of consideration for the effects of the time value of money if the timing of payments provides the Company or the Company's customer with a significant benefit of financing the transfer of goods and services. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less. The Company assesses each of its revenue generating arrangements in order to determine whether a significant financing component exists. The Company recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied, either at a point in time or over time. For performance obligations satisfied over time, the Company measures progress toward completion of its performance obligations using an input method based on the Company's efforts and inputs to satisfy its performance obligations relative to total expected inputs to the satisfaction of that performance obligation.

Amounts received from a customer prior to revenue recognition are recorded as deferred revenue. Amounts received from a customer that are expected to be recognized as revenue within the 12 months following the balance sheet date are classified as a current liability in the accompanying consolidated balance sheets.

Patent costs

The Company expenses patent application and related legal costs as incurred and classifies such costs as general and administrative expenses in the accompanying consolidated statements of operations.

Stock-based compensation

The Company accounts for its stock-based compensation in accordance with ASC Topic 718, *Compensation—Stock Compensation* (ASC 718). ASC 718 requires all share-based payments to employees and directors to be recognized as expense in the consolidated statements of operations and comprehensive loss based on the grant date fair values. The Company adopted FASB Accounting Standards Update (ASU) 2016-09 which identifies areas for simplification of several areas of share-based payment transactions. The Company treats non-employee grants in a manner consistent with employee grants. The Company estimates the fair value of options granted using the Black-Scholes option pricing model for stock option grants to both employees and non-employees. The Company believes the fair value of the stock options granted to non-employees is more reliably determinable than the fair value of the services provided.

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The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including (a) the expected stock price volatility, (b) the expected term of the award, (c) the risk-free interest rate and (d) expected dividends. Due to the lack of sufficient company-specific historical and implied volatility data, the Company has based its computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to the Company, in the stage of product development and life science industry focus. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The Company uses the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, Share-Based Payment, to calculate the expected term for options granted to employees as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The expected term is applied to the stock option grant group as a whole, as the Company does not expect substantially different exercise or post-vesting termination behavior among its employee population. For options granted to non-employees, the Company utilizes the contractual term of the share-based payment as the basis for the expected term assumption. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock.

The Company expenses the fair value of its share-based compensation awards to employees and non-employees on a straight-line basis over the requisite service period, which is generally the vesting period.

Income taxes

The Company accounts for income taxes using the asset and liability method in accordance with ASC Topic 740, *Income Taxes* (ASC 740) which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements on the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies. At December 31, 2022 and 2021, the Company has concluded that a full valuation allowance is necessary for deferred tax assets (see Note 11, *Income taxes*).

Net loss per share

Basic net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share is computed using the weighted-average number of shares of common stock outstanding during the period and, if dilutive, the weighted-average number of potential shares of common stock. Diluted net loss per share is the same as basic net loss per share for the years ended December 31, 2022 and 2021 since all potential shares of common stock instruments are anti-dilutive as a result of the loss for such periods.

Basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	Year Ended December 31,	
	2022	2021
Numerator:		
Net loss	\$ (81,580)	\$ (84,612)
Denominator:		
Weighted-average shares of common stock outstanding-basic and diluted	35,075,924	34,351,200
Net loss per share-basic and diluted	\$ (2.33)	\$ (2.46)

Recently issued and adopted accounting pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company "as-is" condition as of the specified effective date. The Company is an "emerging growth company" as defined 1400 Building Premises Commencement Date; (ii) Landlord shall have no obligation to

for any defects in the Jumpstart Our Business Startups Act of 2012, as amended (Jobs Act). The Jobs Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus,

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an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. The Company elected to avail itself of this extended transition period 1400 Building Premises; and as a result, we will not be required to adopt new or revised accounting standards on relevant dates on which adoption of such standards is required for other public companies.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses* (Topic 326): Measurement of Credit Losses on Financial Instruments. FASB has subsequently issued amendments to ASU 2016-13, which have the same effective date and transition date. These standards require that credit losses be reported using an expected losses model rather than the incurred losses model that was previously used, and establishes additional disclosures related to credit risks available-for-sale debt securities with unrealized losses, this standard now requires allowances to be recorded instead of reducing the amortized cost (iii) Tenant's taking possession of the investment. These standards limit 1400 Building Premises shall be conclusive evidence that Tenant accepts the amount of credit losses to be recognized for available-for-sale debt securities 1400 Building Premises.

Landlord and Tenant acknowledge that (a) Tenant occupied the 1400 Building Premises prior to the amount by which carrying value exceeds fair value and requires 1400 Building Premises Commencement Date pursuant to that certain sublease agreement

between Triplet Therapeutics, Inc. ("Triplet"), the reversal of previously recognized credit losses if fair value increases. The Company adopted this standard on January 1, 2023 and it did not have a material impact on the consolidated financial statements.

10. Employee stock purchase plan

On September 20, 2019, the Company's board of directors and stockholders approved and adopted the 2019 Employee Stock Purchase Plan (ESPP) which became effective on the date same were part of the Company's initial public offering Premises. Tenant shall not make any alterations, additions, or improvements to the Storage Area of shares of its common stock. The ESPP permits participants to purchase common stock through payroll deductions of up to 15% of their eligible compensation. The number of shares of common stock available for issuance under any kind whatsoever. Tenant shall, at Tenant's sole cost and expense, surrender the ESPP will be automatically increased on Storage Area at the first day of each calendar year during the first ten years expiration nor earlier termination of the term of the ESPP, beginning Lease free of any debris and trash and free of any Hazardous Materials in accordance with January 1, the requirements of Section 28 of the Lease. The term of the Lease with respect to the Storage Area shall expire on the expiration or earlier termination of the term of the Lease.

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12. **Lease Modification Fee.** In consideration for Landlord entering into this Second Amendment and ending with January 1, 2029 accelerating the expiration date of the Term of the Lease, Tenant shall be required to pay to Landlord, on or before December 1, 2023, by an amount equal to 1% \$250,000.00 (the "Modification Fee"). For the avoidance of doubt, upon Landlord's receipt of the outstanding number Modification Fee, (i) the Modification Fee shall belong to Landlord and (ii) Landlord shall have no obligation to apply the Modification Fee to any of shares Tenant's obligations under the Lease.
13. **OFAC.** Tenant and all beneficial owners of Tenant are currently (a) in compliance with and shall at all times during the Term of the Company's common stock on December 31 Lease remain in compliance with the regulations of the preceding calendar year Office of Foreign Assets Control ("OFAC") of the U.S. Department of Treasury and any statute, executive order, or such lesser amount regulation relating thereto (collectively, the "OFAC Rules"), (b) not listed on, and shall not during the term of the Lease be listed on, the Specially Designated Nationals and Blocked Persons List, Foreign Sanctions Evaders List, or the Sectoral Sanctions Identification List, which are all maintained by OFAC and/or on any other similar list maintained by OFAC or other governmental authority pursuant to any authorizing statute, executive order, or regulation, and (c) not a person or entity with whom a U.S. person is prohibited from conducting business under the OFAC Rules.
14. **Brokers.** Landlord and Tenant each represents and warrants that it has not dealt with any broker, agent or other person (collectively, "Broker") in connection with the transaction reflected in this Second Amendment and that no Broker brought about this transaction, other than Newmark. Landlord and Tenant each hereby agrees to indemnify and hold the other harmless from and against any claims by any Broker, other than Newmark, claiming a commission or other form of compensation by virtue of having dealt with Tenant or Landlord, as determined applicable, with regard to this Second Amendment.
15. **Miscellaneous.**
 - a. This Second Amendment is the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior and contemporaneous oral and written agreements and discussions. This Second Amendment may be amended only by an agreement in writing, signed by the Company's board parties hereto.

b. This Second Amendment is binding upon and shall inure to the benefit of directors, the parties hereto, and their respective successors and assigns.

The Company's first offering period

c. This Second Amendment may be executed in 2 or more counterparts, each of 2021 concluded on June 30, 2021 which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature process complying with the purchase of 7,064 shares in July 2021 related to this offering period. The Company's second offering period of 2021 concluded on December 31, 2021 with the purchase of 31,832 shares in January 2022. The Company's first offering period of 2022 concluded on June 30, 2022 with the purchase of 44,774 shares in July 2022 related to this offering period. As of December 31, 2022, a total of 1,225,527 shares remain for future offering periods. The Company's second offering period of 2022 concluded on December 31, 2022 with the purchase of 24,754 shares in January 2023 related to this offering.

11. Income taxes

Since inception in 2014, the Company has generated cumulative federal and state net operating loss and research and development credit carryforwards for which the Company has not recorded any net tax benefit due to uncertainty around utilizing these tax attributes within the respective carryforward periods.

As of December 31, 2022, the Company had federal net operating loss carryforwards of approximately \$174,107 and Massachusetts state operating loss carryforwards of approximately \$141,318 which may be available to offset future taxable income. The U.S. federal net operating loss carryforwards include \$22,399 available (ESIGN Act of 2000) or other transmission method and any counterpart so delivered shall be deemed to reduce future taxable income through 2037 have been duly and approximately \$151,708 which do not expire validly delivered and are available to reduce future taxable income indefinitely. The state net operating loss carryforwards are available to offset future taxable income through 2042. As be valid and effective for all purposes. Electronic signatures shall be deemed original signatures for purposes of December 31, 2022, this Second Amendment and all matters related thereto, with such electronic signatures having the Company also had federal same legal effect as original signatures.

d. Except as amended and/or modified by this Second Amendment, the Lease is hereby ratified and Massachusetts research confirmed and development tax credit carryforwards all other terms of \$8,177 the Lease shall remain in full force and \$3,556, respectively, which are available to offset federal effect, unaltered

and state tax liabilities through 2042 and 2037, respectively.

Realization of future tax benefits is dependent on many factors, including the Company's ability to generate taxable income within the net operating loss carryforward period. Net operating loss and tax credit carryforwards may become subject to an annual limitation in unchanged by this Second Amendment. In the event of any conflict between the provisions of this Second Amendment and the provisions of the Lease, the provisions of this Second Amendment shall prevail. Whether or not specifically amended by this Second Amendment, all of the terms and provisions of the Lease are hereby amended to the extent necessary to give effect to the purpose and intent of this Second Amendment

e. Tenant acknowledges that Landlord's business operations are proprietary to Landlord and agrees that Tenant shall hold and require all Tenant Parties to hold in complete confidence and not disclose at any time information regarding any aspect of the business operations of Landlord to any third parties.

[Signatures are on next page]

IN WITNESS WHEREOF, the parties hereto have executed this Second Amendment as of the day and year first above written.

TENANT:

KORRO BIO, INC.,
a Delaware corporation

By: /s/ Ram Aiyar
Name: Ram Aiyar
Its: Chief Executive Officer

☒ I hereby certify that the signature, name, and title above are my signature, name and title.

LANDLORD:

ARE-MA REGION NO. 59, LLC,
a Delaware limited liability company

By: **ALEXANDRIA REAL ESTATE EQUITIES, L.P.,**
a Delaware limited partnership, managing member
By: **ARE-QRS CORP.,**
a Maryland corporation, general partner
By: /s/ Allison Grochola
Name: Allison Grochola
Its: SVP – Real Estate Legal Affairs

EXHIBIT A

DESCRIPTION OF 1400 BUILDING PREMISES

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EXHIBIT B

DESCRIPTION OF STORAGE AREA

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THIRD AMENDMENT TO LEASE

THIS THIRD AMENDMENT TO LEASE (this "Third Amendment") is made as of October 20, 2023, by and between ARE-MA REGION NO. 59, LLC, a Delaware limited liability company ("Landlord"), and KORRO BIO, INC., a Delaware corporation ("Tenant").

RECITALS

A. Landlord and Tenant are now parties to that certain cumulative changes Lease Agreement dated as of August 10, 2020, as amended by that certain First Amendment to Lease dated as of March 2, 2021, and as further amended by that certain Second Amendment to Lease dated as of August 31, 2022 (the "Second Amendment") (as amended, the "Lease"). Pursuant to the Lease, Tenant leases certain premises commonly known as (i) Suite 6-401, containing approximately 12,165 rentable square feet (the "Original Premises") in that certain building located at 600/700 One Kendall Square, Cambridge, Massachusetts (the "600/700 Building"), and (ii) Suite 14-201, containing approximately 10,396 rentable square feet (the "1400 Building Premises"; with the Original Premises, collectively, the "Premises") and that certain storage area commonly known as Suite 14-010, containing approximately 153 rentable square feet (the "Storage Area"), in that certain building located at 1400 One Kendall Square, Cambridge, Massachusetts (the "1400 Building"). The Premises are more particularly described in the ownership interest Lease. Capitalized terms used herein without definition shall have the meanings defined for such terms in the Lease.

B. The Term of significant shareholders over a three-year period the Lease with respect to the entire Premises is scheduled to expire on December 31, 2023 (the "Existing Expiration Date").

C. Landlord and Tenant desire, subject to the terms and conditions set forth below, to amend the Lease to, among other things, extend the Term of the Lease through September 30, 2024 (the "Extended Expiration Date").

NOW, THEREFORE, in excess consideration of 50%, the foregoing Recitals, which are incorporated herein by this reference, the mutual promises and conditions contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant hereby agree as follows:

1. **Term.** The Term of the Lease is hereby extended through the Extended Expiration Date. Tenant's occupancy of the Premises and the Storage Area through the Extended Expiration Date shall be on an "as-is" basis, and Landlord shall have no obligation to provide any tenant improvement allowance or to make any alterations to the Premises or the Storage Area. Tenant shall have no right to extend the Term of the Lease beyond the Extended Expiration Date.

2. **Base Rent.**

a. **Premises.** Tenant shall continue paying Base Rent with respect to the Premises as provided under Sections 382 and 383 in the Lease through the Existing Expiration Date. Commencing on January 1, 2024, Tenant shall pay Base Rent with respect to the Premises in the amount of \$113.00 per rentable square foot of the Code, respectively, as well as similar state provisions. These ownership changes may limit Premises per year.

b. **Storage Area.** Notwithstanding anything to the number of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by contrary contained in Section 382 11 of the Code, results from transactions increasing Second Amendment, commencing on January 1, 2024, Tenant shall pay Base Rent with respect to the ownership of certain shareholders or public groups Storage Area in the stock amount of a corporation by more than 50% over a rolling three-year period. The Company has completed several financings \$56.50 per rentable square foot of the Storage Area per year.

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3. **Operating Expenses and has conducted a study Other Charges.** For the avoidance of doubt, Tenant shall continue to assess whether a change pay Tenant's Share of control has occurred or whether there have been multiple changes 600/700 Building, Tenant's Share of control since inception 1400 Building, and has determined that an ownership change did occur all other amounts due and payable under the Lease as set forth in March 2017. Accordingly, utilization the Lease.

4. **OFAC.** Tenant and all beneficial owners of \$12,400 Tenant are currently (a) in compliance with and shall at all times during the Term of the Lease remain in compliance with the regulations of the Office of Foreign Assets Control ("OFAC") of the U.S. net operating loss carryforwards which were incurred prior to March 2017 (pre-ownership change) is limited under Section 382 Department of Treasury and any statute, executive order, or regulation relating thereto (collectively, the "OFAC Rules"), (b) not listed on, and shall not during the Term of the Code. After Lease be listed on, the limitations Specially Designated Nationals and Blocked Persons List, Foreign

Sanctions Evaders List, or the Sectoral Sanctions Identification List, which are all maintained by OFAC and/or on any other similar list maintained by OFAC or other governmental authority pursuant to any authorizing statute, executive order, or regulation, and (c) not a person or entity with whom a U.S. person is prohibited from conducting business under Section 382 the OFAC Rules.

5. **Brokers.** Landlord and Tenant each represents and warrants that it has not dealt with any broker, agent or other person (collectively, "Broker") in connection with the transaction reflected in this Third Amendment and that no Broker brought about this transaction, other than CBRE and Newmark. Landlord and Tenant each hereby agrees to indemnify and hold the other harmless from and against any claims by any Broker, other than CBRE and Newmark, claiming a commission or other form of compensation by virtue of having dealt with Tenant or Landlord, as applicable, with regard to this Third Amendment.

6. **Miscellaneous.**

a. This Third Amendment is the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior and contemporaneous oral and written agreements and discussions. This Third Amendment may be amended only by an agreement in writing, signed by the parties hereto.

b. This Third Amendment is binding upon and shall inure to the benefit of the Code, the Company parties hereto, and their respective successors and assigns.

c. This Third Amendment may utilize approximately \$10,800 of its pre-ownership change net operating loss carryforwards based upon an annual usage of approximately \$1,600 for be executed in 2 or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the next five years after same instrument. Counterparts may be delivered via electronic mail (including pdf or any electronic signature process complying with the ownership change U.S. federal ESIGN Act of 2000) or other transmission method and approximately \$180any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for each all purposes. Electronic signatures shall be deemed original signatures for purposes of this Third Amendment and all matters related thereto, with such electronic signatures having the same legal effect as original signatures.

d. Except as amended and/or modified by this Third Amendment, the Lease is hereby ratified and confirmed and all other terms of the 15 years thereafter. The remaining pre-March 2017 ownership change net operating losses of approximately \$1,600 were written off due to expiration under limitation. The limitation has been determined Lease shall remain in full force and effect, unaltered and unchanged by first multiplying the value of our stock at the time of the ownership change by the applicable long-term tax-exempt rate. These carryforwards may be subject to further annual limitations under Section 382 of the Code in this Third Amendment. In the event of future changes in ownership. Additionally, any conflict between the Company has determined an ownership changed occurred in October provisions of 2019 as a result this Third Amendment and the provisions of the IPO. Accordingly, utilization Lease, the provisions of approximately \$46,123 of the U.S. net operating loss carryforwards incurred prior to October 2019 is also limited under Section 382 of the Code. The Company has determined it will be able to utilize the entire \$46,123 of its pre-ownership change net operating loss carryforwards based upon the limitations calculated from the October 2019 ownership change. These carryforwards may be subject to further annual limitations under Section 382 of the Code in the event of future changes in ownership.

ASC 740 requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than this Third Amendment shall prevail. Whether or not that some portion or specifically amended by this Third Amendment, all of the deferred tax assets will not be realized. After consideration terms and provisions of all the evidence, both positive and negative, the Company has recorded a valuation allowance against its deferred tax assets at December 31, 2022 and 2021 because the Company's management has determined that it is more likely than not that the Company will not recognize the benefits of its federal and state deferred tax assets primarily due to its cumulative loss position and, as a result, a valuation allowance of approximately \$77,288 and \$50,931 as of December 31, 2022 and 2021 has been established.

The Company has no unrecognized tax benefits. The Company has not, as yet, conducted a study of its research and development credit carryforwards. Such a study may result in an adjustment to the Company's research and development

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credit carryforwards; however, until a study is completed, and any adjustment is known, no amounts Lease are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment were required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the consolidated balance sheet or consolidated statements of operations if an adjustment were required. The Company has elected to recognize interest and penalties related to income tax matters as a component of income tax expense, of which no interest or penalties were recorded for the years ended December 31, 2022 and 2021.

The Company files income tax returns in the U.S. and Massachusetts. The statute of limitations for assessment by the Internal Revenue Service and Massachusetts tax authorities remains open for all years since 2014. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service or state authorities hereby amended to the extent utilized in a future period. No federal or state tax audits are currently in process.

A reconciliation of the Company's pre-tax loss for the years ended December 31, 2022 and 2021 is as follows:

	2022	2021
Domestic	\$ (81,586)	\$ (84,624)
Foreign	4	(47)
Total	\$ (81,582)	\$ (84,671)

The Company's provision at December 31, 2022 and 2021 consist of the following:

	2022	2021
Current:		
Federal	\$ -	\$ -
State	(2)	15
Foreign	-	-
Total current	\$ (2)	\$ 15
Deferred:		
Federal	-	-
State	-	-
Foreign	-	-
Total deferred	\$ -	\$ -
Total (benefit) provision	\$ (2)	\$ 15

A reconciliation of the U.S. federal statutory income tax rate necessary to give effect to the Company's effective income tax rate for the years ended December 31, 2022 purpose and 2021 is as follows:

	2022	2021
U.S federal statutory income tax rate	21.0%	21.0%
Permanent differences	(0.1)	—
State income taxes, net of federal benefit	5.4	2.7
Research and development tax credits	5.1	3.6
State rate changes	3.7	—
Stock compensation deductions	(2.8)	1.6
Other items	—	(0.7)
Change in deferred tax asset valuation allowance	(32.3)	(28.2)
Effective income tax rate	—%	—%

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intent of this Third Amendment.

The Company's deferred tax assets at December 31, 2022e.

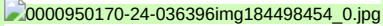
Tenant acknowledges that Landlord's business operations are proprietary to Landlord. Absent prior written consent from Landlord, Tenant shall hold confidential and 2021 consist of the following:

	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	\$ 45,512	\$ 36,590
Research and development tax credits	11,163	7,026
Capitalized research and development costs	10,042	—
Intangibles	478	392
Stock compensation	9,507	6,554
Accrued expenses	—	107
Deferred revenue	—	—
Other	357	176
Fixed assets	282	265
Lease liability	7,735	7,269
Gross deferred tax asset	85,076	58,379
Valuation allowance	(77,288)	(50,931)
Net deferred tax assets	\$ 7,788	\$ 7,448
Deferred tax liabilities:		
Right of use asset	(7,788)	(7,448)
Net deferred tax asset (liability)	\$ -	\$ -

12. Research will not disclose to third parties, and license agreements

Massachusetts Institute of Technology

In December 2016, the Company entered into an exclusive patent license agreement (MIT License Agreement), with the Massachusetts Institute of Technology (MIT), under which the Company received an exclusive, worldwide, royalty-bearing license shall require Tenant's agents, servants, employees, invitees and contractors to certain patent rights hold confidential and not disclose to develop, make, have made, use, sell, offer to sell, lease and import products (Licensed Products) and to develop and perform processes (Licensed Processes) which incorporate the licensed technology for the treatment of disease, third parties, information concerning Landlord's business operations, including but not limited to information regarding the prevention systems, controls, equipment, programming, vendors, tenants, and remediation specialized amenities of hearing loss. The Company also has Landlord.

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IN WITNESS WHEREOF, the right to grant sublicenses of its rights under the MIT License Agreement.

The Company is required to use diligent efforts to develop and commercialize the Licensed Products or Processes, and to make such products or processes reasonably available to the public and to spend certain minimum amounts on research and development of Licensed Products and/or Processes each year until the first commercial sale of a Licensed Product and/or a first commercial performance of a Licensed Process. The Company is also subject to certain development obligations with regards to a first Licensed Product. The Company has satisfied certain obligations related to preclinical studies and the filing of an IND for a first Licensed Product with its development activities related to FX-322. The Company's future development obligations are: (i) to commence a Phase 3 clinical trial for such Product within five years parties hereto have executed this Third Amendment as of the IND filing for such product, (ii) to file day and year first above written.

TENANT:

KORRO BIO, INC.,

a New Drug Application or equivalent with the FDA or comparable European regulatory agency for such Product within nine years of the IND filing for such Product, and (iii) to make a first commercial sale of such Product within 11 years of the IND filing for such Product. The Company also has certain development obligations for a second Licensed Product. In the event Delaware corporation

By: /s/ Ram Aiyyar

Name: Ram Aiyyar

Its: Chief Executive Officer

☐ I hereby certify that the Company has failed to fulfill the development timeline obligation with respect to signature, name, and title above are my signature, name and title.

LANDLORD:

ARE-MA REGION NO. 59, LLC.

a second Licensed Product and fails to cure such breach within ninety (90) days of written notice by MIT, MIT may restrict the licensed field to the prevention and remediation of hearing loss in humans and animals. The Company does not have the right to control prosecution of the in-licensed patent applications, and its rights to enforce the in-licensed patents are subject to certain limitations. Delaware limited liability company

By: Alexandria Real Estate Equities, L.P.,

Upon entering into the MIT License Agreement, the Company paid a \$50 license fee payment and issued to MIT shares of our common stock equal to 5% of total then-outstanding capital stock. The Company is required to pay certain annual license maintenance fees which may be credited to running royalties during the same calendar year, if any, and to make potential milestone payments up to \$2,900 on each Licensed Product or Licensed Process. In addition, the Company is required to pay Delaware limited partnership,

managing member

By: ARE-QRS Corp.,

a low single-digit royalty on Licensed Products and Licensed Processes and a low-twenties royalty on sublicense revenues. Maryland corporation,

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general partner

By: /s/ Scott A. Sherwood

Its: Vice President, Real Estate Legal Affairs

The MIT License Agreement will remain in effect until the expiration or abandonment of all issued patents and filed patent applications licensed thereunder remain in effect, unless terminated earlier. The Company has the right to terminate for any reason upon a 3-month prior written notice. MIT shall have the right to terminate if the Company ceases to carry on any business related to the MIT License Agreement. MIT may terminate the MIT License Agreement for the Company's material breach uncured within ninety (90) days (or thirty (30) days in the case of nonpayment). MIT may also terminate the MIT License Agreement if the Company or our affiliates commence any action against MIT to declare or render any claim of the licensed patent rights invalid, unpatentable, unenforceable, or non-infringed (a patent challenge), or if our sublicensee commences such actions and the Company does not terminate such sublicense within thirty (30) days after MIT's demand. MIT has the right to increase all payments due, instead of terminating the MIT License Agreement in the case of a patent challenge.

In May 2019, the Company entered into an amendment with MIT, updating the diligence milestones for a second Licensed Product.

In March 2022, the Company entered into an amendment with MIT, removing a patent and certain patent applications from the MIT License Agreement which were unrelated to the Company's hearing and MS programs and which were not being utilized by the Company.

The patents in-licensed by the Company from MIT pursuant to the MIT License claim inventions created by, among others, Dr. Langer, one of the Company's directors. Pursuant to MIT's policy on the ownership, distribution and commercial development of MIT technology, or the MIT Policy, inventors of intellectual property invented at MIT, including the inventors of patents licensed to the Company under the MIT License, are entitled to a portion of the net royalty income derived by MIT from such inventions, but not amounts received by MIT from the sale of common stock previously issued by the Company to MIT pursuant to the MIT License. Accordingly, pursuant to the MIT Policy, Dr. Langer is entitled to receive a portion of the amounts the Company pays to MIT under the MIT License, including the Astellas Royalty Payment and future milestone payments or royalties, if any, that the Company may receive pursuant to the Astellas Agreement. Accordingly, Dr. Langer has received \$11 and \$6 from MIT under the MIT Policy during the years ended December 31, 2022 and 2021, respectively. Refer to Note 18, "Related party transactions", for all related party disclosures.

The Scripps Research Institute (California Institute for Biomedical Research)

In September 2018, the Company entered into a license agreement (CALIBR License Agreement) with the California Institute for Biomedical Research (CALIBR) under which the Company received an exclusive, worldwide, royalty-bearing license to certain patent rights to make, have made, use, sell, offer to sell, and import products (CALIBR Licensed Products) which incorporate the licensed technology for the treatment of multiple sclerosis. The Company also have the right to grant sublicenses of our rights under the CALIBR License Agreement. CALIBR reserves the right to use for itself and the right to grant non-exclusive licenses to other nonprofit or academic institutions, for any internal research and educational purposes.

The Company is required to use commercially reasonable efforts to develop, manufacture, and sell at least one CALIBR Licensed Product. The Company is also subject to certain milestone timeline obligations, which may be extended in certain circumstances as set forth in the CALIBR License Agreement. In October 2021, the Company entered into an amendment with CALIBR which updated the milestone obligations to: (i) initiate a Phase 2 clinical trial (or equivalent) for a CALIBR Licensed Product by December 31, 2023 and (ii) initiate a Phase 3 clinical trial (or equivalent) for a CALIBR Licensed Product by December 31, 2025. The Company does not have the right to control prosecution of the in-licensed patent applications, and the Company's rights to enforce the in-licensed patents are subject to certain limitations.

Upon entering into the CALIBR License Agreement, the Company made a \$1,000 license fee payment and is required to make milestone payments up to \$26,000 for each Category of CALIBR Licensed Products (Category 1 is any CALIBR Licensed Products containing a compound that modulates any muscarinic receptor and Category 2 is any CALIBR Licensed Products not included in Category 1 that could differentiate oligodendrocyte precursor cells from *in vitro* studies and/or are active in animal models relevant to MS). The Company is also required to pay a middle single-digit royalty on CALIBR Licensed Products and a royalty on sublicense revenues ranging from low-teen percentage to 50%.

The CALIBR License Agreement shall continue in effect until expiration of all Company obligations to pay royalties. Royalties shall be payable on a country-by-country and CALIBR Licensed Product-by-CALIBR Licensed Product basis upon the later of (1) the expiration or abandonment of all valid claims of the licensed patent rights in such country and (2) ten years from the first commercial sale of each CALIBR Licensed Product. The Company may terminate the CALIBR License Agreement at will upon a 30-day prior written notice. The Company may also elect to terminate its license to one or more

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licensed patents in any or all jurisdictions by giving ninety (90) days' prior written notice to CALIBR. CALIBR may terminate the CALIBR License Agreement for material breach uncured within thirty (30) days. CALIBR has the right to terminate or reduce the license to a non-exclusive license if the Company fails to use diligent efforts to develop and commercially exploit CALIBR Licensed Products.

Massachusetts Eye and Ear (Formerly Massachusetts Eye and Ear Infirmary)

In February 2019, the Company entered into a Non-Exclusive Patent License Agreement (MEE License Agreement) with the Massachusetts Eye and Ear (MEE) under which it received a non-exclusive, non-sublicensable, worldwide, royalty-bearing license to certain patent rights to develop, make, have made, use, sell, offer to sell, lease and import products and to develop and perform processes which incorporate the licensed technology for the treatment or prevention of hearing loss (MEE licensed products).

The Company is obligated to use diligent efforts to develop and commercialize the MEE licensed products. The Company met one of its milestone timeline obligations by dosing a first subject in a Phase 2 trial by December 31, 2020. The Company is still subject to a milestone timeline obligation to dose a first subject in a Phase 3 trial by December 31, 2024. The Company does not control the filing, prosecution, enforcement, and defense of any licensed patent rights.

Upon entering the MEE License, the Company made a \$20 license fee payment. The Company is obligated to pay certain annual license maintenance fees between \$5 and \$7.5 per each MEE patent family case number included in the licensed MEE patent rights prior to first commercial sale of an MEE licensed product. The Company is also obligated to pay a minimum annual royalty payment of \$15 per each MEE patent family case number included in the licensed MEE patent rights after first commercial sale of an MEE licensed product. The Company is also obligated to make milestone payments up to \$350 on each product or process that incorporates the licensed patent rights. In addition, the Company has agreed to pay a low single-digit royalty on products and processes that incorporate the licensed patent rights.

The MEE License Agreement shall remain in effect until all issued patents and filed patent applications within the licensed patent rights have expired or been abandoned, unless terminated earlier. The Company has the right to terminate the MEE License Agreement at will by giving thirty (30) business days advance written notice to MEE. MEE has the right to terminate the MEE License Agreement if the Company fails to make any payment due within thirty (30) business days after MEE notifies the Company of such failure. MEE shall have the right to terminate if the Company fails to maintain the required insurance. MEE shall also have the right to terminate the MEE License Agreement upon forty-five (45) business days written notice if the Company becomes insolvent. MEE has the right to terminate for any other default not cured within sixty (60) business days written notice. MEE also has the right to terminate if the Company or its affiliates challenge the validity of the licensed patent rights.

13. Collaboration agreement

In July 2019, the Company entered into a License and Collaboration Agreement with Astellas (Astellas Agreement), under which the Company granted Astellas an exclusive, royalty-bearing, sub-licensable, nontransferable license to certain patent rights to research, develop, manufacture, have manufactured, use, seek and secure regulatory approval for, commercialize, offer for sale, sell, have sold and import, and otherwise exploit licensed products containing both a GSK-3 inhibitor and an HDAC inhibitor (Astellas Licensed Products), including the product candidate FX-322, outside of the United States. The Company also granted Astellas a right of first negotiation and a right of last refusal if it entered into any negotiation or agreement of any kind (other than an acquisition of all of the stock or assets of the Company) with any third party under which such third party would obtain the right to develop, manufacture, or commercialize Astellas Licensed Products in the United States.

These parties have agreed to use commercially reasonable efforts to carry out development activities assigned to it under an agreed-upon development plan. Astellas has agreed to use commercially reasonable efforts to obtain regulatory approval for at least one Astellas Licensed Product in sensorineural hearing loss and in age-related hearing loss, in each case, in one major Asian country and one major European country. The Company has agreed to use commercially reasonable efforts to obtain regulatory approval for at least one Astellas Licensed Product in the United States. Astellas has the sole right to commercialize the Astellas Licensed Products outside of the United States, and the Company has the sole right to commercialize the Astellas Licensed Products in the United States. Astellas has agreed to use commercially reasonable efforts to commercialize Astellas Licensed Products in a major Asian country and a major European country following receipt of regulatory approval in such countries.

The collaboration is governed by a joint steering committee (JSC) established under the Astellas Agreement and shall

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be comprised of three representatives each from the Company and Astellas. The JSC shall oversee and coordinate the overall conduct of the development, manufacture and commercialization of the Astellas Licensed Products. All decisions of JSC shall be taken through a unanimous vote with each party's representatives collectively having one vote. Both the parties shall be responsible for carrying out the development and manufacturing activities in their defined territory in accordance with the plan as reviewed and approved in the JSC.

As consideration for the licensed rights under the Astellas Agreement, Astellas paid the Company an upfront payment of \$80,000 in July 2019 and has agreed to pay potential development milestone payments up to \$230,000 and commercialization milestones of up to \$315,000. Specifically, the Company would receive development milestone payments of \$65,000 and \$25,000 upon the first dosing of a subject in a Phase 2b clinical trial for SNHL in Europe and Asia, respectively and \$100,000 and \$40,000 upon the first dosing of a subject in a Phase 3 clinical trial for SNHL in Europe and Asia, respectively. If the Astellas Licensed Products are successfully commercialized, the Company would be eligible for up to \$315,000 in potential commercial milestone payments and also tiered royalties at rates ranging from low- to mid-teen percentages. The parties shall share equally, on a 50/50 basis, all out-of-pocket costs and joint study costs for all the joint activities conducted pursuant to the development plans or the joint manufacturing plan.

The Astellas Agreement remains in effect until the expiration of all royalty obligations. Royalties are paid on a licensed product-by-licensed product and country-by-country basis until the latest of (i) the expiration of the last valid claim in the licensed patent rights with respect to such Astellas Licensed Product in such country or (ii) a set number of years from the first commercial sale of such Astellas Licensed Product in such country. Astellas may terminate the Astellas Agreement at will upon 60 days' written notice. Each party has the right to terminate the Astellas Agreement due to the other party's material breach if such breach remains uncured for 90 days (or 45 days in the case of nonpayment) or if the other party becomes bankrupt.

The Astellas Agreement is a collaborative agreement that is within the scope of ASC 808. The Company analyzed the joint research and development activities to assess whether they fall within the scope of ASC 808, and will reassess this throughout the life of the arrangement based on changes in the roles and responsibilities of the parties. Based on the terms of the arrangement as outlined above, both parties are deemed to be active participants in the collaboration. Both parties are performing research and development activities in their defined territory and will be performing joint clinical studies in accordance with the development plan and the study protocol approved by the JSC. Additionally, Astellas and the Company are exposed to significant risks and rewards dependent on the commercial success of any product candidates that may result from the collaboration. As such, the collaboration arrangement is deemed to be within the scope of ASC 808.

The arrangement consists of two components; the license of IP and the research and development activities, including committee participation, to support the co-development and research plan. Under the provisions of ASC 808, the Company has determined that it will apply the guidance in ASC 606 to recognize the revenue related to the license since that component of the arrangement is more reflective of a vendor-customer relationship. The Company determined that the license and the related research and development services associated with the Phase 2a clinical study were not distinct from one another, as the license has limited value to Astellas without the performance of the

research and development activities and the Phase 2a study is essential to the use of the license. As such, the Company determined that these activities should be accounted for as a single combined performance obligation.

Revenue associated with this single performance obligation was recognized as the research and development work was performed, using an input method on the basis of research and development costs incurred to date relative to total research and development costs expected to be incurred. The transfer of control occurred over this time period and, in management's judgment, was the best measure of progress towards satisfying the performance obligation. The Company determined that the period of performance of the research and development services began upon the signing of the Astellas Agreement and continued until the completion of the Phase 2a clinical trial of FX-322 (FX-322-202). The transaction price of \$80,000 was allocated to the single combined performance obligation and recorded as deferred revenue in July 2019 when it was received. This upfront payment was recognized as revenue over the period from July 2019 until June 30, 2021, the completion date of the Phase 2a clinical trial (FX-322-202), using the input method.

The potential development and regulatory milestone payments are fully constrained until the Company can conclude that achievement of the milestone is probable and that it is probable that recognition of revenue related to the milestone will not result in a significant reversal in the amount of cumulative revenue recognized when the uncertainty associated with the variable consideration is ultimately resolved and as such these have been excluded from the transaction price. As part of its evaluation of the constraint, the Company considers numerous factors, including the fact that achievement of the milestones is outside the control of the Company and contingent upon the future success of clinical trials, the licensee's efforts, and the receipt of regulatory approval. Any consideration related to sales-based milestones (including royalties) will be recognized

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when the related sales occur as these amounts have been determined to relate predominantly to the license granted to Astellas and therefore are recognized at the later of when the performance obligation is satisfied, or the related sales of licensed products occur. The Company re-evaluates the transaction price, including its estimated variable consideration included in the transaction price and all constrained amounts, at each reporting period and as uncertain events are resolved or other changes in circumstances occur, and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

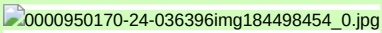
The Astellas Agreement contains joint research and development activities that are not within the scope of ASC 606. The Company will recognize research and development expense related to the joint study costs for all the joint activities in future periods and reimbursements received from Astellas will be recognized as an offset to research and development expense on the consolidated statements of operations during the development period. In the year ended December 31, 2022 and 2021, the Company invoiced Astellas \$392 and \$885 for joint costs.

14. Leases

On December 11, 2020, the Company entered into an Agreement for Termination of Lease and Voluntary Surrender of Premises (Lease Termination Agreement) with ARE-MA Region No. 20, LLC (Landlord) for the Company's office and laboratory space in Woburn, Massachusetts. The Lease Termination Agreement provides that the Lease Agreement, dated as of August 14, 2016, by and between the Company and Landlord (as the same may have been amended, the Lease) will terminate on March 31, 2021, unless the Company elects to extend the term of the Lease. The Company exercised the option to extend the lease until May 31, 2021.

On January 7, 2020 the Company entered into an indenture of lease (Lexington Lease) with HCP/KING 75 Hayden LLC, for the lease of approximately 61,307 square feet of rentable area in Lexington, Massachusetts or (Lexington Premises). The Lexington Lease commenced on December 11, 2020. In the second quarter of 2021, the Company began using the Lexington Premises as its principal executive offices and laboratory for research and development. The term of the Lexington Lease is expected to end on May 31, 2031. The Company also has the option to extend the Initial Term for two additional terms of five years each.

The Company's rent expense for the years ended December 31, 2022 and 2021 was \$4,802 and \$4,960, respectively.

Other information	December 31, 2022
Weighted-average remaining operating lease term	8.4 years
Weighted-average discount rate	8.5 %
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The table below reconciles the undiscounted cash flows to the operating lease liability recorded on the consolidated balance sheet as of December 31, 2022.

2023	4,273
2024	4,402
2025	4,534
2026	4,670
2027	4,810
Thereafter	17,530
Total minimum lease payments	40,219
Less: amount of lease payments representing interest	(11,437)
Present value of future lease payments	28,782

Less: current lease liabilities	(2,021)
Noncurrent lease liabilities	\$ 26,761

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Future aggregate minimum payments under the noncancelable operating lease as of December 31, 2022 are as follows:

2023	\$ 4,273
2024	4,402
2025	4,534
2026	4,670
2027 and beyond	22,340
Total minimum lease payments	\$ 40,219

15. Sublease

On July 8, 2022, the Company entered into a Sublease Agreement with SalioGen Therapeutics, Inc. (SalioGen) to sublease approximately 30,040 rentable square feet of the Company's office space in Lexington, MA for a two-year term. The base sublease rent per month for the first and second year of the sublease is \$197 and \$203, respectively. In addition to base rent, SalioGen will pay 49% of operating costs and taxes payable under the Company's lease for the Lexington, MA office space.

Since commencement, the Company has accounted for the Lexington, MA office space as an operating lease. In accordance with ASC 842, the Company concluded the sublease is also an operating lease. The Company recognized sublease income of \$1,186 for the year ended December 31, 2022. The below table shows the expected future sublease income as of December 31, 2022.

Years Ending December 31,	Sublease Income
2023	\$ 2,371
2024	1,383
Total future sublease income	\$ 3,754

16. Commitments and contingencies

Contract commitments

The Company enters into contracts in the normal course of business with CROs, CMOs, universities, and other third parties for preclinical research studies, clinical trials and testing and manufacturing services. These contracts generally do not contain minimum purchase commitments and are cancelable by us upon prior written notice although, purchase orders for clinical materials are generally non-cancelable. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including non-cancelable obligations of our service providers, up to the date of cancellation or upon the completion of a manufacturing run.

Guarantees

The Company has identified the guarantees described below as disclosable, in accordance with ASC 460, *Guarantees*.

As permitted under Delaware law, the Company indemnifies its officers and directors for certain events or occurrences while the officer or director is, or was, serving at the Company's request in such capacity. The maximum potential amount of future payments the Company could be required to make is unlimited; however, the Company has directors' and officers' insurance coverage that should limit its exposure and enable it to recover a portion of any future amounts paid.

The Company is a party to a number of agreements entered into in the ordinary course of business that contain typical provisions that obligate the Company to indemnify the other parties to such agreements upon the occurrence of certain events. Such indemnification obligations are usually in effect from the date of execution of the applicable agreement for a period equal to the applicable statute of limitations. The aggregate maximum potential future liability of the Company under such indemnification provisions is uncertain.

The Company leases office space in Lexington, Massachusetts under a ten-year noncancelable lease. The \$1,699 security deposit for this lease is classified as restricted cash as of December 31, 2022. The Company exited the Woburn, Massachusetts facility in the second quarter of 2021. The Company has standard indemnification arrangements under these

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leases that require it to indemnify the landlord against all costs, expenses, fines, suits, claims, demands, liabilities, and actions directly resulting from any breach, violation, or nonperformance of any covenant or condition of the lease.

As of December 31, 2022 and 2021, the Company had not experienced any losses related to these indemnification obligations, and no material claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves have been established.

Legal Contingencies

The Company accrues a liability for legal contingencies when it believes that it is both probable that a liability has been incurred and that the Company can reasonably estimate the amount of the loss. The Company reviews these accruals and adjusts them to reflect ongoing negotiations, settlements, rulings, advice of legal counsel and other relevant information. To the extent new information is obtained and the views on the probable outcomes of claims, suits, assessments, investigations or legal proceedings change, changes in the Company's accrued liabilities would be recorded in the period in which such determination is made.

In addition, in accordance with the relevant authoritative guidance, for any matters in which the likelihood of material loss is at least reasonably possible, the Company will provide disclosure of the possible loss or range of loss. If a reasonable estimate cannot be made, however, the Company will provide disclosure to that effect. The Company expenses legal costs as they are incurred.

On June 3, 2021 and June 22, 2021, purported stockholders of the Company filed putative class action lawsuits in the U.S. District Court for the District of Massachusetts against the Company and the Company's Chief Executive Officer, President, and Director, David Lucchino. On March 21, 2022, the two lawsuits were consolidated into a single lawsuit, *Quinones et al. v. Frequency Therapeutics, Inc. et al.* and on May 16, 2022, the Company's Chief Development Officer, Dr. Carl LeBel, was added as a defendant. The plaintiffs allege violations of Sections 10(b), 20(a) and Rule 10b5 of the Securities Exchange Act of 1934, as amended (the Exchange Act), due to allegedly false and misleading statements and omissions about the Company's Phase 2a clinical trial (FX-322-202) for its product candidate FX-322 in the Company's public disclosures between October 29, 2020 and March 22, 2021. The lawsuit seeks, among other things, damages in connection with the Company's allegedly artificially inflated stock price between October 29, 2020 and March 22, 2021 as a result of those allegedly false and misleading statements and omissions, as well as interest, attorneys' fees and costs. The Company intends to vigorously defend against all claims asserted in the lawsuit. The Company filed a motion to dismiss the Amended Complaint on July 15, 2022. This matter is at the very early stages of the legal process, and as a result, the Company is not able to estimate a range of possible loss. Since an estimate of the possible loss or range of loss cannot be made at this time, no accruals have been recorded as of December 31, 2022.

On June 21, 2022, the Delaware Chancery Court dismissed a lawsuit brought by two purported stockholders against the Company and others. For previously reported information on this lawsuit, refer to Part I, Item 3, "Legal Proceedings" of the Company's 2021 Form 10-K. On August 16, 2022, these same two purported stockholders of the Company filed a similar lawsuit in Delaware Superior Court against (i) the Company, (ii) Computershare Inc., and (iii) Computershare Trust Company, N.A., entitled *The Gregory J. Parseghian Revocable Trust, et al. v. Frequency Therapeutics, Inc., et al.* The lawsuit alleges causes of action against the Company for breach of the statutory duty of care, negligence, conversion, and unjust enrichment, based on allegations that actions were taken to prevent the purported stockholders from selling their shares in the Company. The Company intends to vigorously defend against all claims asserted in the lawsuit. This matter is at the very early stages of the legal process, and as a result, the Company is not able to estimate a range of possible loss. Since an estimate of the possible loss or range of loss cannot be made at this time, no accruals have been recorded as of December 31, 2022.

On June 30, 2022, a purported stockholder of the Company filed a shareholder derivative complaint in the U.S. District Court for the District of Delaware purportedly on the Company's behalf against members of the Company's board of directors and the Company as a nominal defendant, entitled *Dewey v. Cohen et al.* The complaint alleges (i) violations of Section 10(b) and Rule 10b5 of the Exchange Act, (ii) breach of fiduciary duty, (iii) aiding and abetting breach of fiduciary duty, (iv) unjust enrichment, and (v) waste of corporate assets. The claims are based on the same underlying allegations as the *Quinones* case (described above). The complaint seeks, among other things, monetary damages, interest, attorneys' fees and costs. On September 27, 2022, this lawsuit was stayed pending resolution of the *Quinones* case. This matter is at the very early stages of the legal process, and as a result, the Company is not able to estimate a range of possible loss. The Company's board members are each party to an indemnification agreement with the Company that may require the Company to

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reimburse the board members for certain expenses and other costs related to this lawsuit. Since an estimate of the possible loss or range of loss cannot be made at this time, no accruals have been recorded as of December 31, 2022.

17. Employee benefit plan

Employees of the Company are eligible to participate in the Company's 401(k) retirement plan (401(k) Plan). Participants may contribute up to 90% of their annual compensation to the 401(k) Plan, subject to statutory limitations. Under the 401(k) Plan Safe Harbor Match, the Company matches 100% of the first 5% of employee contributions and vests 100% at time of match. For the years ended December 31, 2022 and 2021, the Company made matching contributions of \$550 and \$723, respectively.

18. Related party transactions

As disclosed in Note 12, "Research and license agreements", the Company entered into the MIT License Agreement in December 2016. The patents in-licensed by the Company from MIT pursuant to the MIT License Agreement claim inventions created by, among others, Dr. Langer, one of the Company's directors. Accordingly, Dr. Langer has received \$11 and \$6 from MIT under the MIT Policy during the years ended December 31, 2022 and 2021, respectively.

The Company's lease for its Woburn, Massachusetts facility, terminated in May 2021 as disclosed in Note 14, "Leases", was with an entity affiliated with one of the Company's directors and shareholders.

19. Subsequent events

The Company has evaluated subsequent events for recognition, remeasurement and disclosure purposes through March 10, 2023, the date which the consolidated financial statements were available to be issued. The identified subsequent event is as follows:

On February 13, 2023, the Company announced a restructuring in which its hearing program was discontinued. As a result, the Company reduced its workforce by approximately 55% to better align with the needs of its business. The total personnel costs related to the restructuring are estimated to be approximately \$4,000 in future cash outlays primarily related to severance costs and related expenses.

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Exhibit 21.1

Subsidiaries of Frequency Therapeutics, Inc.

Legal Name of Subsidiary		Jurisdiction of Incorporation or Organization
Korro Bio Ops, Inc.	Delaware	
Korro Mass Securities, Inc.	Massachusetts	
Frequency Therapeutics Pty Ltd		Australia
Frequency Therapeutics Securities Corporation		Massachusetts

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (No. (Form S-1 No. 333-248474) on Form S-1, the Registration Statement (No. 333-250099) on Form S-3, and the Registration Statement (No. 333-234128) on Form S-8 of Frequency Therapeutics, Inc.;
- (2) Registration Statement (Form S-1 No. 333-275353) of Korro Bio, Inc.;
- (3) Registration Statement (Form S-8 No. 333-275354) pertaining to the 2019 Stock Incentive Plan of Korro Bio Ops, Inc., 2023 Stock Option and Incentive Plan and 2023 Employee Stock Purchase Plan of Korro Bio, Inc.;
- (4) Registration Statement (Form S-8 No. 333-263643) pertaining to the 2019 Incentive Award Plan and 2019 Employee Stock Purchase Plan of Frequency Therapeutics, Inc.; and
- (5) Registration Statement (Form S-8 No. 333-234128) pertaining to the 2014 Stock Incentive Plan, as amended, 2019 Incentive Award Plan and 2019 Employee Stock Purchase Plan of Frequency Therapeutics, Inc.

of our report dated March 10, 2023 March 26, 2024, relating with respect to the consolidated financial statements of Frequency Therapeutics, Korro Bio, Inc., appearing included in this Annual Report on Form 10-K (Form 10-K) of Frequency Therapeutics, Korro Bio, Inc. for the year ended December 31, 2022 December 31, 2023.

/s/ RSM US Ernst & Young LLP

Boston, Massachusetts
March 10, 202326, 2024

Exhibit 31.1

CERTIFICATIONS

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULE 13a-14(a) / RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, David L. Lucchino, Ram Aiyar, certify that:

- 1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2023 of Frequency Therapeutics, Korro Bio, Inc. (the "registrant");
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

- (a) a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- (b) b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- (c) c. Evaluated the effectiveness of the registrant's registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- (d) d. Disclosed in this report any change in the registrant's registrant's internal control over financial reporting that occurred during the registrant's registrant's most recent fiscal quarter (the registrant's registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's registrant's internal control over financial reporting; and
5. The registrant's registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's registrant's audit and the audit committee of the registrant's registrant's board of directors (or persons performing the equivalent functions):
- (a) a. All all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's registrant's ability to record, process, summarize and report financial information; and
- (b) b. Any any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's registrant's internal control over financial reporting.

Date: March 10, 2023

By:

/s/ David L. Lucchino Ram Aiyar

David L. Lucchino Ram Aiyar

President and Chief Executive Officer

(Principa

I

Executiv

e Officer)

Dated: March 26, 2024

Exhibit 31.2

CERTIFICATIONS

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULE 13a-14(a) / RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Richard Mitrano, Vineet Agarwal, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2023 of Frequency Therapeutics, Korro Bio, Inc. (the "registrant");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rule: 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) c. Evaluated the effectiveness of the registrant's registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) d. Disclosed in this report any change in the registrant's registrant's internal control over financial reporting that occurred during the registrant's registrant's most recent fiscal quarter (the registrant's registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's registrant's internal control over financial reporting; and
5. The registrant's registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's registrant's audit and the audit committee of the registrant's registrant's board of directors (or persons performing the equivalent functions):
 - (a) a. All all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's registrant's ability to record, process, summarize and report financial information; and
 - (b) b. Any any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's registrant's internal control over financial reporting.

Date: March 10, 2023

By:

/s/ Richard Mitrano Vineet Agarwal

Richard Mitrano Vineet Agarwal

Chief
Financial
Officer
Vice
President
t,
Finance
and
Operatio
ns
(Princip
al
Financi
al and
Account
ing
Officer)

Dated: March 26, 2024

Exhibit 32.1

CERTIFICATION CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Frequency Therapeutics, Korro Bio, Inc. (the "Company") on Form 10-K for the period fiscal year ended December 31, 2022 December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David L. Lucchino, the undersigned hereby certify, pursuant to 18 U.S.C. § Section 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my their knowledge:

- (1) The the Report fully complies with the requirements of section Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The the information contained in the Report fairly presents, in all material respects, the financial condition and result results of operations of the Company.

Date: March 10, 2023

B /s/ David L.
y Lucchino Ram
Aiyar
David L.
Lucchino Ram
Aiyar
President and
Chief Executive
Officer

(principal executive officer) Principal
Executive Officer)

Dated: March 26, 2024

/s/ Vineet Agarwal
Vineet Agarwal

Dated: March 26, 2024

Exhibit 32.2

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with This certification accompanies the Annual Report of Frequency Therapeutics, Inc. (the "Company") on Form 10-K for the period ended December 31, 2022 as to which it relates, is not deemed filed with the Securities and Exchange Commission on and is not to be incorporated by reference into any filing of Korro Bio, Inc. under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date hereof (the "Report"), I, Richard Mitrano, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act Form 10-K), irrespective of 2002, that, to any general incorporation language contained in such filing.

Exhibit 97.1

KORRO BIO, INC.

COMPENSATION RECOVERY POLICY

Adopted as of November 3, 2023

Korro Bio, Inc., a Delaware corporation (the "Company"), has adopted a Compensation Recovery Policy (this "Policy") as described below.

1. Overview

The Policy sets forth the best of my knowledge:

(1) The Report fully complies circumstances and procedures under which the Company shall recover Erroneously Awarded Compensation from Covered Persons (as defined below) in accordance with rules issued by the requirements of section 13(a) or 15(d) of United States Securities and Exchange Commission (the "SEC") under the Securities Exchange Act of 1934, as amended; amended (the "Exchange Act"), and the Nasdaq Stock Market. Capitalized terms used and not otherwise defined herein shall have the meanings given in Section 3 below.

2. Compensation Recovery Requirement

In the event the Company is required to prepare a Financial Restatement, the Company shall recover reasonably promptly all Erroneously Awarded Compensation with respect to such Financial Restatement.

3. Definitions

- a. "Applicable Recovery Period" means the three completed fiscal years immediately preceding the Restatement Date for a Financial Restatement. In addition, in the event the Company has changed its fiscal year: (i) any transition period of less than nine months occurring within or immediately following such three completed fiscal years shall also be part of such Applicable Recovery Period and (ii) any transition period of nine to 12 months will be deemed to be a completed fiscal year.
- (2) b. The information contained in "Applicable Rules" means any rules or regulations adopted by the Report fairly presents, in all material respects, Exchange pursuant to Rule 10D-1 under the financial condition Exchange Act and result any applicable rules or regulations adopted by the SEC pursuant to Section 10D of operations the Exchange Act.

- c. "Board" means the Board of Directors of the Company.
- d. "Committee" means the Compensation Committee of the Board or, in the absence of such committee, a majority of independent directors serving on the B
- e. "Covered Person" means any Executive Officer. A person's status as a Covered Person with respect to Erroneously Awarded Compensation shall be determined as of the time of receipt of such Erroneously Awarded Compensation regardless of the person's current role or status with the Company (e.g., if a person begins service as an Executive Officer after the beginning of an Applicable Recovery Period, that person would not be considered a Covered Person with respect to Erroneously Awarded Compensation received before the person began service as an Executive Officer, but would be considered a Covered Person with respect to Erroneously Awarded Compensation received after the person began service as an Executive Officer where such person served as an Executive Officer any time during the performance period for such Erroneously Awarded Compensation).
- f. "Effective Date" means October 2, 2023.
- g. "Erroneously Awarded Compensation" means the amount of any Incentive-Based Compensation received by a Covered Person on or after the Effective Date and during the Applicable Recovery

Date: March 10, 2023

By:

/s/ Richard Mitrano

Richard Mitrano

Vice President, Finance and Operations

(principal financial officer and principal accounting officer)

Period that exceeds the amount that otherwise would have been received by the Covered Person had such compensation been determined based on the restated amounts in a Financial Restatement, computed without regard to any taxes paid. Calculation of Erroneously Awarded Compensation with respect to Incentive-Based Compensation based on stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in a Financial Restatement, shall be based on a reasonable estimate of the effect of the Financial Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was received, and the Company shall maintain documentation of the determination of such reasonable estimate and provide such documentation to the Exchange in accordance with the Applicable Rules. Incentive-Based Compensation is deemed received, earned or vested when the Financial Reporting Measure is attained, not when the actual payment, grant or vesting occurs.

- h. "Exchange" means the Nasdaq Stock Market LLC.
- i. An "Executive Officer" means any person who served the Company in any of the following roles at any time during the performance period applicable to Incentive-Based Compensation and received Incentive-Based Compensation after beginning service in any such role (regardless of whether such Incentive-Based Compensation was received during or after such person's service in such role): the president, principal financial officer, principal accounting officer (if there is no such accounting officer the controller), any vice president in charge of a principal business unit, division or function (such as sales, administrative or finance), any other officer who performs a policy making function or any other person who performs similar policy making functions for the Company. Executive officers of parents or subsidiaries of the Company may be deemed executive officers of the Company if they perform such policy making functions for the Company.
- j. "Financial Reporting Measures" mean measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, any measures that are derived wholly or in part from such measures (including, for example, a non-GAAP financial measure and stock price and total shareholder return).
- k. "Incentive-Based Compensation" means any compensation provided, directly or indirectly, by the Company or any of its subsidiaries that is granted, earned or vested based, in whole or in part, upon the attainment of a Financial Reporting Measure and any other equity-based compensation provided by the Company or any of its subsidiaries, including, without limitation, stock options, restricted stock awards, restricted stock units and stock appreciation rights.
- l. A "Financial Restatement" means a restatement of previously issued financial statements of the Company due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required restatement to correct an error in previously-issued financial statements that is material to the previously-issued financial statements or that would result in a material misstatement if the error were corrected in the current period and not corrected in the current period.
- m. "Restatement Date" means, with respect to a Financial Restatement, the earlier of: (i) the date the Board concludes, or reasonably should have concluded, that the Company is required to prepare the Financial Restatement or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare the Financial Restatement.

4. Exception to Compensation Recovery Requirement

The Company may elect not to recover Erroneously Awarded Compensation pursuant to this Policy if the Committee determines that recovery would be impracticable, and one or more of the following conditions, together with any further requirements set forth in the Applicable Rules, are met: (i) the direct expense paid to a third party, including outside legal counsel, to assist in enforcing this Policy would exceed the amount to be recovered, and the

Company has made a reasonable attempt to recover such Erroneously Awarded Compensation or (ii) recovery would likely cause an otherwise tax-qualified retirement plan to fail to be so qualified under applicable regulations.

5. Tax Considerations

To the extent that, pursuant to this Policy, the Company is entitled to recover any Erroneously Awarded Compensation that is received by a Covered Person, the gross amount received (i.e., the amount the Covered Person received, or was entitled to receive, before any deductions for tax withholding or other payments) shall be returned to the Covered Person.

6. Method of Compensation Recovery

The Committee shall determine, in its sole discretion, the method for recovering Erroneously Awarded Compensation hereunder, which may include, without limitation, any one or more of the following:

- a. requiring reimbursement of cash Incentive-Based Compensation previously paid;
- b. seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer or other disposition of any equity-based awards;
- c. cancelling or rescinding some or all outstanding vested or unvested equity-based awards;
- d. adjusting or withholding from unpaid compensation or other set-off;
- e. cancelling or offsetting against planned future grants of equity-based awards; and/or
- f. any other method permitted by applicable law or contract.

Notwithstanding the foregoing, a Covered Person will be deemed to have satisfied such person's obligation to return Erroneously Awarded Compensation to the Company if such Erroneously Awarded Compensation is returned in the exact same form in which it was received; provided that equity withheld to satisfy tax obligations will be deemed to have been received in cash in an amount equal to the tax withholding payment made.

7. Policy Interpretation

This Policy shall be interpreted in a manner that is consistent with the Applicable Rules and any other applicable law. The Committee shall take into consideration any applicable interpretations and guidance of the SEC in interpreting this Policy, including, for example, in determining whether a financial restatement qualifies as a Financial Restatement hereunder. To the extent the Applicable Rules require recovery of Incentive-Based Compensation in additional circumstances besides those specified above, nothing in this Policy shall be deemed to limit or restrict the right or obligation of the Company to recover Incentive-Based Compensation to the fullest extent required by the Applicable Rules.

8. Policy Administration

This Policy shall be administered by the Committee; provided, however, that the Board shall have exclusive authority to authorize the Company to prepare a Financial Restatement. In doing so, the Board may rely on a recommendation of the Audit Committee of the Board. The Committee shall have such powers and authorities related to the administration of this Policy as are consistent with the governing documents of the Company and applicable law. The Committee shall have full power and authority to take, or direct the taking of, all actions and to make all determinations required or provided for under this Policy and shall have full power and authority to take, or direct the taking of, all such other actions and make all such other determinations not inconsistent with the specific terms and provisions of this Policy that the Committee deems to be necessary or appropriate to the administration of

this Policy. The interpretation and construction by the Committee of any provision of this Policy and all determinations made by the Committee under this policy shall be final, binding and conclusive.

9. Compensation Recovery Repayments not Subject to Indemnification

Notwithstanding anything to the contrary set forth in any agreement with, or the organizational documents of, the Company or any of its subsidiaries, Covered Persons are not entitled to indemnification for Erroneously Awarded Compensation or for any losses arising out of or in any way related to Erroneously Awarded Compensation recovered under this Policy.