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DELTA REPORT

10-K

FATE - FATE THERAPEUTICS INC

10-K - DECEMBER 31, 2023 COMPARED TO 10-K - DECEMBER 31, 2022

The following comparison report has been automatically generated

TOTAL DELTAS	4260
CHANGES	236
DELETIONS	1738
ADDITIONS	2286

REFINITIV

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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

☐ **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 001-36076

FATE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**65-1311552**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
12278 Scripps Summit Drive, San Diego, California	**92131**
(Address of principal executive offices)	**(Zip Code)**

(858) 875-1800

(Registrant's telephone number, including area code)

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 par value	**FATE**	**NASDAQ Global Market**

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

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

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

Indicate by check mark whether the 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 was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ or No ☐

Indicate by check mark whether the 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 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. ☐

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) 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 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 Act). Yes ☐ No ☒

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately $2,340,000,000 462,000,000 as of June 30, 2022 June 30, 2023 based upon the closing sale price on The Nasdaq Global Market reported for such date. Shares of common stock held by each executive officer and director and certain holders of more than 10% of the outstanding shares of the registrant's common stock have been excluded in that such persons may be deemed to be affiliates. Shares of common stock held by other persons, including certain other holders of more than 10% of the outstanding shares of common stock, have not been excluded in that such persons are not deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, as of February 22, 2023 February 20, 2024 was 98,161,823 99,237,508.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission, or SEC, on or before the date 120 days after the conclusion of the registrant's fiscal year ended December 31, 2022 December 31, 2023 pursuant to Regulation 14A, in connection with the registrant's 2023 2024 Annual Meeting of Stockholders are incorporated by reference into Part III of this annual report on Form 10-K.

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FATE THERAPEUTICS, INC.
Annual Report on Form 10-K
For the Fiscal Year Ended December 31, 2022 December 31, 2023

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RISK FACTOR SUMMARY

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the Securities and Exchange Commission (SEC) before making investment decisions regarding our common stock.

- Development of our product candidates will require substantial additional funding, which, if available, may cause dilution to our stockholders, and without which we wil unable to complete preclinical or clinical development of, or obtain regulatory approval for, our product candidates, and we may not be able to secure adequate fundin acceptable terms or on a timely basis.
- Our product candidates and programs represent a novel therapeutic approach approaches to treating cancer and autoimmune disorders disease, and our product candidates may cause undesirable side effects or have other properties that could delay or halt their preclinical or clinical development, prevent their regulatory approv limit their commercial potential or result in significant negative consequences. If we fail to complete the preclinical or clinical development of, or to obtain regulatory ap for, our product candidates on a timely basis or at all, our business would be significantly harmed.
- We useOur proprietary induced pluripotent stem cell (iPSC) product platform enables the production of next-generation product candidates, and we have multiple iPSC-derived NK cell and T-cell product candidates currently undergoing clinical development. We may elect to deprioritize or discontinue the clinical development of one or more of our product candidates for any number of reasons, including due to changes in our business strategy, in our prioritization of our product candidates, and the competitive therapeutic landscape for which our product candidates are being developed. In addition, one or more of our product candidates undergoing clinical development may have therapeutic potential in more than one disease area, and we may elect to discontinue clinical development in one disease area in order to pursue the development of such product candidate in another disease area.
- We use iPSC technology and gene-editing technology in the creation of our product candidates. Both technologies are relatively new technologies, which makes it diff predict the time and cost of product candidate development and obtaining regulatory approval. If we are unable to use these technologies in the creation of our produc candidates, our business would be significantly harmed.
- We may face delays in initiating, conducting or completing our clinical trials, including due to difficulties enrolling patients in our clinical trials, securing manufacturing adequate clinical supply of our product candidates, and obtaining sufficient quantities of other components and supplies necessary for the conduct of our clinical trials, including agents such as cyclophosphamide or fludarabine which are often required to condition patients for treatment with our product candidates, or certain monoclo antibodies which are intended for administration to patients in combination with our product candidates in certain of our clinical trials, and we may not be able to initiat conduct or complete them our clinical trials at all.
- Initial, interim and preliminary data from our preclinical studies or clinical trials that we announce or publish from time to time may change as more patient data becom available and are subject to audit and verification procedures that could result in material changes in the final data. Furthermore, results from our ongoing or future clir trials involving our product candidates may differ materially from initial, interim and preliminary data.
- The manufacture and distribution of our cell product candidates are complex and subject to a multitude of risks. These risks could substantially limit the clinical and commercial supply of our product candidates and increase our costs, and the development and commercialization of our product candidates could be significantly dela or restricted if the United States Food and Drug Administration (FDA) or other regulatory authorities impose additional requirements on our manufacturing operations c are required to change our manufacturing operations to comply with regulatory requirements.
- We have limited experience manufacturing our product candidates on a clinical scale, and no experience manufacturing on a commercial scale. Any failure by us or a third parties on whom we depend to manufacture sufficient quantities of our product candidates consistently and under the proper conditions at acceptable quality and may result in delays to our clinical development plans and impair our ability to obtain approval for, or commercialize, our product candidates.

- Our inability to manufacture sufficient quantities of our product candidates or the loss of our third-party contract manufacturers, or our or their failure to supply sufficien quantities of our product candidates at acceptable quality levels or prices, or at all, and would materially and adversely affect our business.
- We depend on third party third-party suppliers, including sole source suppliers, for the provision of reagents, materials, devices and equipment that are used by us and third-party contract manufacturers in the production of our product candidates, the loss of which could adversely impact our ability to conduct our clinical trials or commercialize our product candidates, if approved.
- The ongoing global COVID-19 pandemic, caused by the coronavirus, SARS-CoV-2, and global political and market instability, including as a result of the ongoing conf Ukraine, could adversely impact various aspects of our business, results of operations and financial condition, and could cause a disruption to our supply chain and th development and manufacture of our product candidates.
- We may face challenges recruiting and retaining key personnel due to labor market changes, availability of qualified candidates, and competition for employees from c companies.

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- We may face cost fluctuations and inflationary pressures, including increases in prices of materials and costs of labor, which may adversely impact our operating performance, expenses, cash utilization and results.

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- We depend on strategic partnerships and collaboration arrangements for the development and commercialization of certain of our product candidates in certain indica or geographic territories, and if these arrangements are unsuccessful or are terminated, this could result in delays and other obstacles in the development, manufactu commercialization of any of our product candidates and materially harm our results of operations.
- Development of our product candidates will require substantial additional funding, without which we will be unable to complete preclinical or clinical development of, or obtain regulatory approval for, our product candidates, and we may not be able to secure adequate funding on acceptable terms or on a timely basis.
- We have a limited operating history, have incurred significant losses since our inception, and anticipate that we will continue to incur significant losses for the foreseea future, including in connection with the potential global development of our product candidates.
- If we are unable to protect our intellectual property or obtain and maintain patent protection for our technology and product candidates, other companies could develop products based on our technologies and discoveries, which may reduce demand for, or limit the commercial potential of, our products and harm our business.
- If we fail to comply with our obligations under our license agreements, we could lose rights to our product candidates or key technologies.
- We may not be successful in obtaining or maintaining necessary rights to product components and processes for development or manufacture of our product candidat which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.
- We do not have experience marketing any product candidates and do not have a sales force or distribution capabilities, and if our products are approved, we may be u to commercialize them successfully.
- The commercial success of our product candidates will depend upon the degree of market acceptance by physicians, patients, third-party payers and others in the me community and may require additional generation of additional evidence development around areas like to support the anticipated short-term and long-term costs, comparative risks and benefits relative to standard of care and emerging therapies, and other value demonstrations.
- We face increasing competition in an environment of rapid technological change from other biotechnology and pharmaceutical companies, and our operating results w suffer if we fail to compete effectively.
- The success of our existing and any future product candidates is substantially dependent on developments within the field fields of cellular immunotherapy cancer and autoimmunity, and to on changes to the competitive therapeutic landscape and clinical treatment standards, some the majority of which are beyond our control.
- Security breaches, loss of data and other disruptions could compromise sensitive information related to our business.
- Our principal stockholders and management own a significant percentage of our stock and may be able to exercise significant control over our company.
- Our stock price is subject to fluctuation based on a variety of factors.
- Global economic and market conditions, any continued and prolonged public health emergency similar to the COVID-19 pandemic, wars and armed conflicts, includin ongoing wars between Russia and Ukraine and between Israel and Hamas, could adversely impact various aspects of our business, results of operations and financia condition, and could cause disruptions to our supply chain and the development and manufacture of our product candidates.

The summary risk factors described above should be read together with the text of the full risk factors below, in the section entitled "Risk Factors", and the other information set forth in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes, as well as in other documents that we file with the SEC. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations and future growth prospects.

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FORWARD–LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties, as well as assumptions that, even if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Annual Report on Form 10-K are forward-looking statements. In some cases, you can identify forward-looking statements by words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “will,” “would,” or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our plans to research, develop and commercialize our product candidates;
- the initiation, timing, progress, success, cost size, duration, costs and timing results of our clinical trials and preclinical studies for our product development activities; candidates;
- our ability and timing to advance our product candidates in, and to successfully initiate, conduct, enroll and complete, clinical trials;
- the therapeutic potential of our product candidates, and the disease indications for which we intend to develop our product candidates;
- the timing and likelihood of, and our ability to obtain and maintain, regulatory clearance of our Investigational New Drug (IND) applications for and regulatory approval product candidates;
- the potential of our technology platform, including our induced pluripotent stem cell (iPSC) iPSC product platform, and our ability to leverage our platform in our resear development and commercialization activities for our product candidates;
- our ability to manufacture our product candidates for clinical development and, if approved, for commercialization, and the timing and costs of such manufacture;
- our ability to source clinical and, if approved, commercial materials and supplies used to manufacture our product candidates;
- the performance of third parties in connection with the development and manufacture of our product candidates, including third parties conducting our clinical trials as as third-party suppliers and manufacturers; suppliers;
- our ability to attract, successfully partner with, and retain strategic collaborators with development, regulatory and commercialization expertise;
- the potential benefits of strategic collaboration agreements and our ability, and the ability of our collaborators, to successfully develop product candidates under the respective collaborations;
- our ability to obtain funding for our operations, including funding necessary to initiate and complete clinical trials of our product candidates;
- our ability to develop sales and marketing capabilities, whether alone or with actual or potential collaborators, to commercialize our product candidates, if approved;
- our ability to successfully commercialize our product candidates, if approved;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;
- regulatory developments and approval pathways in the United States and foreign countries for our product candidates;
- the potential scope and value of our intellectual property rights;
- our ability, and the ability of our licensors, to obtain, maintain, defend and enforce intellectual property rights protecting our product candidates, and our ability to devel and commercialize our product candidates without infringing the proprietary rights of third parties;
- our ability to recruit and retain key personnel;
- the accuracy of our projections and estimates regarding our revenues, expenses, capital requirements, cash utilization and need for additional financing;

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- our ability to compete with rapidly evolving cell therapy therapeutic technologies and respond to other developments relating to our competitors and our industry; and

- other risks and uncertainties, including those described under Part I, Item 1A. Risk Factors of this Annual Report on Form 10-K.

Any forward-looking statements in this Annual Report on Form 10-K reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part I, Item 1A. Risk Factors and elsewhere in this Annual Report on Form 10-K. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

In this Annual Report on Form 10-K, unless the context requires otherwise, "Fate Therapeutics," "Company," "we," "our," and "us" means Fate Therapeutics, Inc. and its subsidiaries.

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PART I

ITEM 1. Business

Overview

We are a clinical-stage biopharmaceutical company dedicated to bringing a first-in-class pipeline of programmed cellular immunotherapies to patients with cancer and autoimmune disorders. diseases. Our development of first-in-class cell therapy product candidates programmed cellular immunotherapies is based on a simple notion: we believe that better cell therapies start with better cells.

To create better cell therapies, we have pioneered a therapeutic approach that we generally refer to as cell programming: we create and engineer human induced pluripotent stem cells (iPSCs) to incorporate novel synthetic controls of cell function; we generate a clonal master iPSC line for use as a renewable source of cell manufacture; and we direct the fate of the clonal master iPSC line to produce our first-in-class cell therapy product candidate. Analogous to master cell lines used to manufacture biopharmaceutical drug products such as monoclonal antibodies, we believe clonal master iPSC lines can be used to mass produce multiplexed-engineered, cellular immunotherapies which are well-defined and uniform in composition, can be stored in inventory for off-the-shelf availability, can be combined and administered with other standard-of-care therapies, and can have broader significant patient reach.

Utilizing this therapeutic approach, our proprietary iPSC product platform, we are advancing a cell therapy pipeline comprised of off-the-shelf, multiplexed-engineered iPSC-derived natural killer (NK) cell and T-cell product candidates that which are selectively designed, incorporate novel synthetic controls of cell function, and are intended to deliver multiple mechanisms of therapeutic importance mechanisms to patients for the treatment of cancer and autoimmune disease. We have a deep pipeline of iPSC-derived, chimeric antigen receptor (CAR)-targeted NK cell and T-cell product candidates currently under development with multiple clinical trials ongoing:

Program	Indication	CAR Target(s)	# of Synthetic Controls	Development Stage	Partner
CAR NK Cell Programs	***Oncology - Hematologic Malignancies***				
FT576 FT819	Multiple Myeloma B-cell Malignancies	BCMA CD19	4 2	Phase 1	
FT522	B-cell Lymphoma	CD19; 41BB	5	Preclinical	
Autoimmune Disorders	CD19; 41BB	5	Preclinical		
CAR T-cell Programs					

FT819	B-cell Lymphoma	CD19	2	Phase 1	
	Chronic Lymphocytic Leukemia FT576	CD19 Multiple Myeloma	2 BCMA	4	Phase 1
Oncology - Solid Tumors					
FT825	Solid Tumors	HER2	7	Preclinical Phase 1	Ono
Other CAR-targeted Programs					
Undisclosed	Solid Tumors	Not disclosed	Not disclosed	Preclinical	Ono
Autoimmune Diseases					
FT819	Systemic Lupus Erythematosus	CD19	2	Phase 1	
FT522	Undisclosed	CD19; 41BB	5	Preclinical	

Our Approach

The use of human cells as therapeutic entities has disease-transforming potential, and compelling evidence of medical benefit for cell therapy exists across a broad spectrum of severe, life-threatening diseases. Clinical investigation of cellular immunotherapy has been rapidly expanding. One particular form of cell-based cancer immunotherapy, CAR T-cell therapy, has emerged as a revolutionary and potentially curative therapy treatment for patients with certain hematologic malignancies, including refractory cancers. malignancies. In fact, multiple CAR T-cell therapies have now been approved by the United States Food and Drug Administration (FDA) for the treatment of relapsed / refractory B-cell precursor acute lymphoblastic leukemia (ALL), relapsed / refractory diffuse large B-cell lymphoma, relapsed / refractory follicular lymphoma, relapsed / refractory mantle cell lymphoma, malignancies and relapsed / refractory multiple myeloma.

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Cell-based cancer immunotherapies undergoing clinical investigation today most often rely on the use of autologous, or a patient's own, cells. The requirement to source, engineer, expand and deliver cells patient-by-patient is logistically complex, resource intensive and expensive, and can result in significant batch-to-batch variability in product identity, purity and potency as well as in manufacturing failures. Significant hurdles remain to ensure that cell-based cancer immunotherapies can be consistently manufactured and reliably delivered in a cost-effective manner and at the scale necessary to support broad patient access and widespread commercialization. Rather than rely on the use of a patient's own cells, we seek to use clonal master iPSC lines to manufacture, develop and commercialize off-the-shelf cellular immunotherapies that are selectively designed, incorporate novel synthetic controls of cell function, and are intended to deliver multiple mechanisms of therapeutic importance to patients.

Human iPSCs possess the unique dual properties of unlimited self-renewal and differentiation potential into all cell types of the body. Our proprietary iPSC product platform combines multiplexed-engineering of human iPSCs with single-cell selection to create clonal master iPSC lines. Analogous Rather than rely on the use of donor cells, or a patient's own cells, we seek to master cell lines used to manufacture biopharmaceutical drug products such as monoclonal antibodies, use clonal master iPSC lines can be used for to manufacture, develop and commercialize CAR NK cell and CAR T-cell product candidates which are selectively designed, incorporate novel synthetic controls of multiplexed-engineered cell products that are well-defined and uniform in composition, function, can be mass produced at significant scale in a cost-effective manner, are well-defined and uniform in composition, and can be stored in inventory and delivered off-the-shelf to maximize patient reach. As a result, we We believe our platform therapeutic approach is uniquely designed to overcome numerous limitations associated with the production of cell therapies using patient- or donor-sourced cells. Our proprietary iPSC product platform is supported by an intellectual property portfolio of over 400 500 issued patents and 450 500 pending patent applications.

Our Strategy

Our goal mission is to maintain and build upon our leadership position in bringing bring off-the-shelf, multiplexed-engineered, iPSC-derived cellular immunotherapy immunotherapies with disease-transforming potential to patients with cancer and autoimmune disorders. We believe achieving this goal has the potential to transform patient outcomes by improving cell product consistency and potency, shortening time to treatment, enabling combination with other complementary therapies, increasing scale of manufacture while reducing production costs, and reaching more patients including earlier in care. diseases. The key pillars of our strategy include:

- **Capitalize on Advance our leadership position in industry-leading iPSC technology. product platform.** Human iPSCs, with their unique capacity to be indefinitely expanded and differentiated in culture into any cell type of cell in the body, hold revolutionary potential for creating better cell therapies. The groundbreaking discovery that fully differentiated fully-differentiated human cells can be induced to a pluripotent state through the expression of certain genes was recognized with the 2012 Nobel Prize in Science and Medicine. We believe iPSCs can be used to overcome key limitations inherent in many to the manufacture,

development and commercialization of the today's cell therapy product candidates undergoing development today, therapies, including the requirement to source, isolate, engineer and expand cells from an individual patient or healthy donor with each batch of production. These batch-to-batch manufacturing requirements are logistically complex and expensive, and can result in variable cell product identity, purity and potency as well as manufacturing failures.

We are applying our expertise in have established a proprietary iPSC biology to genetically engineer, isolate product platform and select single-cell iPSCs for clonal expansion, characterization and cryopreservation as clonal master iPSC lines. Analogous to master cell lines used to manufacture biopharmaceutical drug products such as monoclonal antibodies, we believe clonal master iPSC lines can be used to mass produce multiplexed-engineered cellular immunotherapies which incorporate novel synthetic controls of cell function, are well-defined and uniform in composition, can be stored in inventory for off-the-shelf availability, can be combined and administered with other therapies, and can have broader patient reach.

We have amassed significant internal expertise in the Good Manufacturing Practice (GMP) production of off-the-shelf, multiplexed-engineered, iPSC-derived NK cells and T cells from clonal master iPSC lines. T-cell product candidates for therapeutic use. Our proprietary know-how iPSC product platform includes: generating, engineering, isolating and characterizing single-cell iPSC clones; creating, qualifying, and cryopreserving clonal master iPSC lines; differentiating these clonal master cell iPSC lines to manufacture produce NK cells and T T-cells at scale; cryopreserving and storing iPSC-derived NK cells at large scale to enable off-the-shelf availability for the general patient population; and T-cells under conditions that support multi-year stability; applying our regulatory experience and quality expertise to enable clinical investigation of off-the-shelf, multiplexed-engineered, iPSC-derived NK cell and T-cell cellular immunotherapy candidates. We have established and operate our own fully-integrated infrastructure Good Manufacturing Practice (GMP) facility for scaled manufacture of iPSC-derived NK cells and operations T-cells, which is intended to support GMP production for all phases of clinical development as well as initial commercialization.

- **Exploit Apply our proprietary iPSC product platform to develop and commercialize off-the-shelf, iPSC-derived, CAR NK cells in combination with monoclonal antibody therapy to mount a multi-antigen targeted attack. cell-based cancer immunotherapies.** NK cells play a major role in the anti-tumor activity of certain tumor-targeting antibodies. NK cells express CD16, an activating receptor that binds to the Fc domain of IgG antibodies. Once activated through CD16, NK cells are able to destroy antibody-coated tumor cells and secrete cytokines, such as interferon gamma, to potentiate an adaptive immune response. This mechanism of action, referred to as antibody-dependent cellular cytotoxicity (ADCC), is believed to be important for the treatment of a wide range of cancers. CD16 consists of two genomic variants, 158V and 158F, that confer high or low binding affinity, respectively, to the Fc domain of IgG antibodies. Numerous clinical trials with FDA-approved tumor-targeting antibodies, including rituximab (FDA-approved for certain cancers of the blood and lymphatic system), trastuzumab (FDA-approved for certain breast and gastric cancers) and cetuximab (FDA-approved for certain head and neck, non-small cell lung and colorectal cancers), have demonstrated

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that patients homozygous for the 158V variant, which is present in only about 15% of patients, have improved clinical outcomes. In addition, the expression of CD16 on NK cells has been shown to undergo considerable down-regulation in cancer patients, which can significantly limit anti-tumor activity.

Our off-the-shelf, multiplexed-engineered, iPSC-derived CAR NK cell product candidates incorporate a proprietary CD16 Fc receptor, which has two unique features designed to augment ADCC: a high-affinity homozygous 158V variant to promote high binding affinity and a modification to block its cleavage and down-regulation upon NK cell activation. As a result, we believe our iPSC-derived CAR NK cell product candidates may be combined with monoclonal antibody (mAb) therapy to target more than one antigen expressed on tumor cells, which may lead to deeper and more durable responses. For example, the CD38-targeted mAb therapy daratumumab is approved for the treatment of multiple myeloma and has been shown to induce cell death through multiple mechanisms, including ADCC. However, because CD38 is also expressed on the body's activated NK cells, daratumumab treatment can induce NK cell fratricide, which may impair the effectiveness of ADCC. In addition, NK cell function is often suppressed or absent in patients with multiple myeloma as a result of the cancer itself as well as treatment therapy, further reducing the effectiveness of daratumumab. FT576, our iPSC-derived, BCMA-targeted CAR NK cell product candidate for the treatment of multiple myeloma, incorporates four novel synthetic controls of cell function and is specifically designed to be administered in combination with CD38-targeted mAb therapy, and our clinical development strategy for FT576 involves assessing the unique therapeutic benefit of dual-antigen targeting of BCMA and CD38 expressed on plasma cells.

- **Bring off-the-shelf, iPSC-derived CAR T cells to patients with hematologic malignancies and solid tumors.** Autologous While autologous CAR T-cell therapies targeting CD19 for the treatment of B-cell lymphoma and targeting BCMA for the treatment of multiple myeloma have emerged as highly effective treatments for patients with relapsed / refractory disease. Despite their potent activity, widespread hematologic malignancies, adoption of FDA-approved CAR T-cell therapy has been relatively modest to date due to complex logistics, high cost, manufacturing capacity constraints, and toxicities that necessitate administration only in large hospitals and treatment centers with intensive care units, as compared to more accessible community hospitals and outpatient infusion centers. According to a survey of academic centers in the U.S. that specialize in administering CD19-targeted and community hospitals. In addition, autologous CAR T-cell therapy, only about half of eligible patients receive the treatment, with only 12% of patients able to receive treatment within one month. We believe these limitations provide the opportunity for development of an off-the-shelf CAR T-cell therapy that can be delivered faster, more reliably, at greater scale, and at lower cost with the ability to reach more patients. To that end, we are clinically investigating FT819 which, to our knowledge, is the first-ever off-the-shelf, iPSC-derived CAR T-cell therapy candidate to undergo clinical investigation, in a multi-center Phase 1 study for the treatment of adult patients with relapsed / refractory B-cell malignancies, including B-cell lymphoma and chronic lymphocytic leukemia. FT819 incorporates two novel synthetic controls of cell function: a novel 1XX CAR construct inserted directly into the T-cell receptor alpha constant (TRAC) locus that targets CD19; and the complete disruption of T-cell receptor (TCR) expression for the prevention of graft-versus-host disease (GvHD), a potentially life-threatening complication associated with allogeneic T-cell therapy.

We are also conducting preclinical development of multiplexed-engineered, iPSC-derived, CAR T-cell therapy candidates therapies for the treatment of solid tumors where the application of autologous CAR T-cell therapy has have been significantly hampered by tumor-associated antigen heterogeneity, inefficient CAR T-cell

trafficking to the tumor, and immunosuppression inherent to the tumor microenvironment. Our first microenvironment, and there are no FDA-approved CAR T-cell therapies for the treatment of solid tumors.

We believe there is significant opportunity for the development of iPSC-derived, cell-based cancer immunotherapies which have the potential to be selectively designed to incorporate multiple therapeutic mechanisms of action, stored in inventory for off-the-shelf availability, and combined and administered with standard-of-care, outpatient treatment regimens to increase patient reach. We are currently advancing multiple off-the-shelf, multiplexed-engineered, iPSC-derived CAR NK cell and CAR T-cell cancer immunotherapy candidates in first-in-human clinical studies. In conducting these studies of our product candidates, we seek to treat patients with cancer who are relapsed or refractory to FDA-approved therapies where the unmet need is high. We also seek to mount a multi-antigen attack against cancer by combining our product candidates with standard-of-care therapies, such as monoclonal antibody therapy. To this end, we have incorporated a proprietary high-affinity, non-cleavable CD16 (hnCD16) Fc receptor into several of our CAR-targeted cell product candidates, which receptor has two unique features designed to augment antibody-dependent cellular

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cytotoxicity (ADCC): a high-affinity homozygous 158V variant to promote binding to the Fc domain of IgG antibodies, and a modification to block its cleavage and down-regulation upon receptor activation. As a result, certain of our CAR NK cell and CAR T-cell product candidate, FT825, is designed candidates target more than one antigen expressed on tumor cells in combination with monoclonal antibody therapy, which may lead to target human epidermal growth factor deeper and more durable responses in cancer patients. Additionally, in the setting of solid tumors, we also seek to overcome certain of the key limitations that have stifled anti-tumor activity of autologous CAR T-cell therapy by incorporating novel synthetic receptors into our cell product candidates including, for example, a novel synthetic CXCR2 receptor 2 (HER2)-expressing solid tumors. FT825 incorporates seven to promote effector cell trafficking to the tumor site and a novel synthetic TGFβ receptor to resist immunosuppressive signals in the tumor microenvironment.

- **Expand the potential therapeutic reach of our off-the-shelf, iPSC-derived CAR NK cell and CAR T-cell product candidates to patients with severe, life-threatening autoimmune diseases.** Autoimmune diseases affect organs throughout the body and are often characterized by the presence of auto-antibodies, which are produced by aberrant B cells and can attack healthy cells and tissues. The chronic and debilitating nature of autoimmune diseases leads to both high medical costs and reduced quality of life, creating a significant burden for patients, their families and the health care system. Over 80 diseases are classified as autoimmune diseases affecting up to 8% of the U.S. population. Despite the availability of many approved drugs, there remains substantial unmet clinical need, as existing therapies are rarely considered curative and the majority of patients do not adequately respond to these therapies.

  In a ground-breaking academic clinical study published in Nature Medicine in September 2022, an investigational autologous CD19-targeted CAR T-cell therapy was administered to five patients with systemic lupus erythematosus (SLE). Rapid B-cell depletion and elimination of auto-antibody production was observed following infusion of therapy, and all patients achieved clinical remission with significant improvement in Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) score. Given that the targeting and rapid depletion of B cells are common mechanisms of action for the successful treatment of B-cell malignancies and certain autoimmune diseases, we believe that our off-the-shelf CAR NK cell and CAR T-cell product candidates may be uniquely suited to address a broad range of autoimmune diseases through the potential reset of the CD19+ B-cell lineage. We are currently conducting study start-up of a multi-center, Phase 1 clinical trial of our FT819 CAR T-cell program for the treatment of patients with moderate to severe SLE, including those with active lupus nephritis or with active extrarenal lupus. In addition, we are currently assessing the potential to expand our FT522 and FT576 CAR NK programs beyond oncology into autoimmunity, including each program's potential to treat certain autoimmune diseases by more broadly targeting autoantibody-producing lineages.

- **Discover and incorporate novel synthetic controls of cell function including a synthetic CXCR2 receptor to promote cell trafficking and a synthetic TGFβ receptor to redirect immunosuppressive signals in the tumor microenvironment. Under our collaboration with Ono Pharmaceutical Co. Ltd. (Ono), we are currently conducting Investigational New Drug (IND)-enabling activities for FT825, and plan to submit an IND application to the FDA in 2023 to enable the initiation of first-in-human clinical investigation for the treatment of certain solid tumors.**

- **Continue to incorporate novel synthetic controls into our off-the-shelf, iPSC-derived cellular immunotherapy CAR NK cell and CAR T-cell product candidates to that significantly expand patient reach and disease application. enhance therapeutic differentiation.** We believe off-the-shelf, iPSC-derived cellular immunotherapy has the unique potential to incorporate a multitude of novel synthetic controls that could deliver multiple mechanisms of therapeutic importance to patients, enable safe and effective combination with early line, standard-of-care treatment regimens, and allow for administration in the community setting on an outpatient basis. One of the most significant barriers that limit patient reach and disease application of cellular immunotherapy is the requirement for patients receiving

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CAR T-cell therapy, whether autologous or allogeneic, to receive and endure intense systemic lympho-conditioning, which is conditioning chemotherapy. Conditioning chemotherapy often results in severe blood cell deficiencies and related toxicities, thereby requiring administration in large hospitals and can prevent treatment centers with intensive care units, and prevents effective combination with early line, standard-of-care treatment regimens.regimens widely used in the community setting. We are exploring the integration of novel synthetic controls which into our iPSC product platform that may enable our off-the-shelf, iPSC-derived cellular immunotherapy cell product candidates to be administered without intense conditioning chemotherapy conditioning and as part in the community setting on an outpatient basis. We believe that the use of standard-of-care immunomodulatory regimens. a more tolerable treatment paradigm for cellular immunotherapies may significantly expand patient reach and enhance therapeutic differentiation.

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For example, we have incorporated allo-immune FT522 is our first iPSC-derived cell product candidate to incorporate our novel alloimmune defense receptor (ADR) technology, licensed from which is designed to reduce or eliminate the Baylor College need for administration of Medicine into intense conditioning chemotherapy to patients receiving cellular immunotherapy. FT522 our iPSC-derived, CD19-targeted CAR incorporates a synthetic ADR receptor that targets the cell surface receptor 4-1BB (CD137), a member of the tumor necrosis factor receptor superfamily that is upregulated on activated CD4+, CD8+, and regulatory T-cells as well as activated NK cell product candidate. This technology cells of the host immune system. The ADR receptor is designed to (a) selectively recognize and destroy allo-reactive alloreactive host immune cells that would otherwise be capable of rejecting the product candidate, (b) maintain other components of the host immune system to preserve hematopoietic cell function, and (c) activate the product candidate to enhance its potency and persistence. Published preclinical studies have shown that ADR-armed allogeneic cells are protected from both T- and NK-cell mediated rejection (Mo et al. *Nature Biotechnology*, 39, 56–63 (2021)), providing proof-of-concept that ADR-armed allogeneic cells can persist and function in immunocompetent patients.

We are currently conducting IND-enabling activities believe we have the opportunity to establish clinical proof-of-concept for our ADR technology early in dose escalation of our ongoing multi-center, Phase 1 study for FT522 and plan to submit an IND application to the FDA in 2023 to enable the initiation of first-in-human clinical investigation for the treatment of relapsed / refractory B-cell lymphoma in combination with CD20-targeted mAb therapy. lymphoma. In addition, to our plans for the clinical investigation of FT522 in relapsed / refractory B-cell lymphoma, we are preclinically assessing the potential to expand our FT522 program beyond oncology into autoimmunity. We believe the novel synthetic controls of FT522, in combination with CD38-targeted mAb therapy, may be uniquely suited to address a broad range of autoimmune diseases and disorders by resetting both of these autoantibody-producing lineages through the dual-targeting of CD19-expressing B cells and CD38-expressing plasma cells, leading to more complete removal of autoantibodies and improved clinical outcomes. diseases.

- **Efficiently develop and commercialize first-in-class, iPSC-derived cellular immunotherapies for severe, life-threatening diseases.** We are clinically developing first-in-class, iPSC-derived cellular immunotherapies to improve the lives of patients with severe, life-threatening diseases. We seek to prioritize indications for development where the unmet need is significant and where regulatory agencies offer expedited development and review programs. For example, for patients who have relapsed or are refractory to autologous CD19-targeted CAR T-cell therapy, the prognosis is dismal and survival is measured in weeks to months. No standard therapies are available for these post-CAR T-cell therapy patients, and recent retrospective analyses of real-world data presented at the 2021 American Society of Hematology Annual Meeting showed extremely poor treatment outcomes with complete response rates of administered therapies ranging from 5% to 25% and overall survival ranging from 5.2 months to 7.5 months. We believe a single-arm study in a relatively small number of patients may serve as a potential registrational pathway for the treatment of these patients.
- **Selectively share our proprietary iPSC product platform with strategic partners.**The research, development and clinical investigation commercialization of cell therapies for the treatment of human diseases is rapidly expanding. We believe we are well positioned to form partnerships with third parties seeking to develop and commercialize iPSC-derived cellular immunotherapies cell therapies for the treatment of human diseases, including cancer. diseases. For example, we are collaborating with Ono to research and develop and commercialize off-the-shelf,

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multiplexed-engineered, iPSC-derived CAR NK cell and CAR T-cells T-cell product candidates for the treatment of certain solid tumors. In addition, since iPSCs have the unique capacity to be genetically engineered, indefinitely expanded and differentiated in culture into any type of cell in the body, we believe there is significant opportunity to broadly exploit our iPSC product platform and intellectual property position in other disease areas beyond cancer. In 2022, we formed Senescea Therapeutics, Inc., a majority-owned subsidiary of the Company, with Memorial Sloan Kettering Cancer Center (MSKCC) to research and develop iPSC-derived cell therapies for the treatment of diseases associated with cell

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senescence. We will continue to seek partnerships with companies and institutions for the research, development and commercialization of iPSC-derived cell therapies for the treatment of human diseases.

Our Off-the-shelf, Multiplexed-engineered, iPSC-derived Cellular Immunotherapy Pipeline

Utilizing our proprietary iPSC product platform, we are developing off-the-shelf, multiplexed-engineered CAR NK cell and CAR T-cell product candidates for the treatment of cancer and autoimmune diseases. Our iPSC-derived cell product candidates are selectively designed to incorporate novel synthetic controls of cell function, can be mass produced at significant scale in a cost-effective manner, are well-defined and uniform in composition, and can be stored in inventory and delivered off-the-shelf to maximize patient reach. We believe our therapeutic approach is uniquely designed to overcome numerous limitations associated with the production of cell therapies using patient- or donor-sourced cells.

FT819: CAR T-cell Program

FT819 is our first iPSC-derived CAR T-cell product candidate and, to our knowledge, is the first-ever iPSC-derived CAR T-cell product candidate to undergo clinical investigation in the world. FT819 was developed under an ongoing sponsored research collaboration with MSKCC that is being led by Michel Sadelain, M.D., Ph.D., Director of the Center for Cell Engineering and the Stephen and Barbara Friedman Chair at MSKCC. Dr. Sadelain was awarded the 2024 Breakthrough Prize in Life Sciences for trailblazing the development of CAR T-cell immunotherapy.

We have exclusively licensed from MSKCC foundational intellectual property covering iPSC-derived cellular immunotherapy, including T-cells and NK cells derived from iPSCs engineered with CARs, for human therapeutic use. We have an innate ability also licensed from MSKCC intellectual property covering compositions of novel CAR constructs, including the use of a novel 1XX co-stimulatory domain, and of genetically engineered CAR T-cells, including methods of making these cells using CRISPR for certain targeted gene modifications. Embodiments of this additional intellectual property include preclinical data published by Dr. Sadelain demonstrating that directing a CD19-specific CAR to rapidly seek the T-cell receptor alpha chain (TRAC) locus resulted in uniform CAR expression in human peripheral blood T-cells, enhanced T-cell potency, and destroy abnormal cells, such delayed effector T-cell differentiation and exhaustion (Eyquem et al. Nature. 543, 113–117, 2017), and that CAR T-cells utilizing a novel 1XX CAR signaling domain exhibited enhanced antitumor activity, persistence and long-term cytotoxicity as cancer or virally-infected cells, and represent one of the body's first lines of immunological defense. NK cells have the unique ability to selectively identify and destroy abnormal cells through multiple mechanisms while leaving normal healthy cells unharmed. These cytotoxic mechanisms include: direct innate killing by binding to stress ligands expressed by abnormal cells and releasing toxic granules; indirect killing by producing and releasing proinflammatory and chemotactic cytokines that play well as a pivotal role decrease in orchestrating the adaptive immune response; and antibody-mediated targeted killing by binding to and enhancing the activity of endogenous and therapeutic antibodies through ADCC. T-cell exhaustion (Feucht et al. *Nature Medicine*. 25, 82–88, 2019).

T FT819 incorporates two novel synthetic controls of cell function: a novel 1XX CAR construct inserted directly into the TRAC locus that targets CD19; and the complete disruption of TCR expression for the prevention of graft-versus-host disease (GvHD), a potentially life-threatening complication associated with allogeneic T-cell therapy. Together, these features of FT819 are designed to induce antigen-specific cytotoxicity, enhance CAR activity through TRAC-regulated expression, and mitigate risk of GvHD. In preclinical studies, we have shown that iPSC-derived TCR-CAR+ CAR T-cells targeting CD19:

- displayed antigen-specific anti-tumor potency *in vitro*, including cytokine release and targeted cellular cytotoxicity, comparable to peripheral blood CD19-specific CAR T-cells;
- did not respond or proliferate against HLA-mismatched (CD19-) peripheral blood mononuclear cells or T-lymphocytes, play as targets in a critical role mixed lymphocyte reaction, indicating the risk of GvHD is alleviated;
- controlled tumor progression in adaptive immunity vivo comparable to peripheral blood CD19-specific CAR T-cells in a preclinical mouse model of acute lymphoblastic leukemia; and
- enhanced tumor clearance and durable control of leukemia *in vivo*, as compared to primary CAR19 T-cells, in a xenograft mouse model of disseminated lymphoblastic leukemia.

Additional preclinical data published in August 2022 showed the generation of iPSC-derived TCR-CAR+ CD8αβ T-cells, which were able to repeatedly lyse tumor cells *in vitro* and durably control leukemia *in vivo*, with persistence in the bone marrow, spleen, and blood, in a systemic NALM6 leukemia model (Sjoukje et al. *Nature Biomedical Engineering.* 6, 1284–1297, 2022).

We are distinguished from other cells of currently evaluating FT819 in an ongoing, multi-center, Phase 1 clinical trial to assess its safety, pharmacokinetics, clinical activity, and to determine the immune system by recommended Phase 2 dose, in patients with relapsed / refractory B-cell malignancies, including B-cell lymphoma (BCL). In addition, we have expanded our clinical investigation into autoimmune diseases. In July 2023, the presence FDA allowed our Investigational New Drug (IND) application for the conduct of a T-cell receptor (TCR) on their surface. TCRs are generated by DNA rearrangement multi-center, Phase 1 clinical trial of FT819 to assess its safety and positively selected for their capacity clinical activity, and to engage host major histocompatibility complex (MHC) molecules. The majority of T cells, termed alpha beta T cells (αβ T cells), rearrange their alpha and beta chains on determine the TCR, which confers specificity and enables T cells recommended Phase 2 dose, in patients with moderate to recognize non-self molecules, known as non-self antigens, expressed on the surface of target cells. Antigens inside a target cell are bound to, and are routinely brought to the surface of a cell, by MHC class I molecules. Upon antigen recognition, T cells bind to the MHC-antigen complex, become

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activated and destroy the targeted cell. Unlike NK cells, T cells are limited by antigen-specific binding of their TCR in order to induce cellular cytotoxicity. severe SLE, including those with active lupus nephritis or active extrarenal lupus.

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B-cell Malignancies

At the 2022 American Society of Hematology (ASH) Annual Meeting, we presented interim clinical data for 8 patients with aggressive large B-cell lymphoma (LBCL) treated with a single dose of FT819 in our ongoing Phase 1 study (see table below). Patients were heavily pre-treated having received a median of 4.5 prior lines of therapy (range 3-7), including 6 of 8 patients (75%) having previously received autologous CD19-targeted CAR T-cell therapy. Each of the 8 patients received standard conditioning chemotherapy consisting of cyclophosphamide (Cy) at 500 mg/m^2 and fludarabine (Flu) at 30 mg/m^2 for three days followed by a single dose of FT819 ranging from 90 million cells to 360 million cells. As of a September 8, 2022 data cutoff date:

- *Tolerability.* The FT819 treatment regimen was well tolerated. No dose-limiting toxicities (DLTs), and no Grade 3 or greater FT819-related treatment-emergent adverse events (TEAEs) or serious TEAEs, were observed. With respect to TEAEs of special interest, there were no observations of immune effector-cell associated neurotoxicity syndrome (ICANS) or GvHD, and one patient experienced Grade 2 cytokine release syndrome (CRS). There were no study discontinuations or deaths due to TEAEs.
- *Activity.* One of two patients naïve to CAR T-cell therapy achieved an objective response at Day 30, which was a complete response (CR) in a patient with diffuse large B-cell lymphoma (DLBCL) previously treated with 5 prior lines of therapy; and two of six patients previously treated with CAR T-cell therapy achieved an objective response at Day 30, which included a CR in a patient with DLBCL previously treated with 7 prior lines of therapy who did not respond to autologous CD19-targeted CAR T-cell therapy.

Aggressive Large B-cell Lymphoma[1,2,3]						
FT819 Regimen A: Single Dose (n=8)						
	CAR T-cell Therapy Naïve			Prior CAR T-cell Therapy		
Cells	90M	180M	360M	90M	180M	360M
N	1	n/a	1	4	1	1
OR / CR	0 / 0	n/a	1 / 1	2 / 1	0 / 0	0 / 0

OR = objective response; **CR**= complete response; **M** = million

1 As of data cutoff date of September 8, 2022

2 Includes diffuse large B-cell lymphoma and high-grade B-cell lymphoma

3 Day 30 protocol-defined response assessment per Lugano 2014 criteria

We amended the FT819 clinical protocol to allow for the use of bendamustine at 90 mg/m^2 for two days as an alternative to Cy / Flu conditioning chemotherapy. Dose escalation in the multi-center, Phase 1 clinical trial of FT819 is currently ongoing at a single dose of FT819 at 1.08 billion cells for BCL. We currently do not plan to assess FT819 at a dose level above 1.08 billion cells, and any further clinical development of FT819 in patients with relapsed / refractory B-cell malignancies will be determined upon completion of the dose escalation at this current dose level.

Autoimmune Diseases

Autoimmune diseases affect organs throughout the body and are developing often characterized by the presence of auto-antibodies, which are produced by aberrant B cells and can attack healthy cells and tissues. In a first-in-class cell ground-breaking academic clinical study published in *Nature Medicine* in September 2022, an investigational autologous CD19-targeted CAR T-cell therapy pipeline comprised was administered to five patients with SLE. Rapid B-cell depletion and elimination of off-the-shelf, multiplexed-engineered, auto-antibody production was observed following infusion of therapy, and all patients achieved clinical remission with significant improvement in SLEDAI-2K score. Naïve B-cell reconstitution occurred after an average time of 110 days of CAR T-cell infusion.

Given that the targeting and rapid depletion of B cells is a common mechanism of action for the successful treatment of B-cell malignancies and certain autoimmune diseases, we are expanding our clinical investigation of FT819 to autoimmune diseases. We are currently conducting study start-up of a multi-center, Phase 1 clinical trial of FT819 for the treatment of patients with moderate to severe SLE, including those with active lupus nephritis or with active extrarenal lupus. We intend to treat patients with standard conditioning chemotherapy followed by a single dose of FT819, with dose

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escalation initiating at 360 million cells. Primary endpoints include the incidence of adverse events and the frequency of dose-limiting toxicities, and secondary endpoints include characterizing pharmacokinetics and pharmacodynamics, assessing disease-related biomarkers, and evaluating efficacy.

We believe FT819 has potential applicability across multiple autoimmune diseases.

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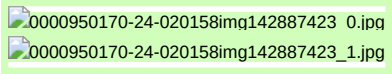
FT825: CAR T-cell Program

FT825 is our first iPSC-derived CAR NK cell and CAR T-cell product candidates that candidate for the treatment of solid tumors being developed in collaboration with Ono Pharmaceutical. The use of autologous CAR T-cell therapies for the treatment of solid tumors has been hampered by tumor-associated antigen heterogeneity, inefficient CAR T-cell trafficking to the tumor, immunosuppression inherent to the tumor microenvironment, and differentiating tumor-associated antigen expression between tumor and normal tissue. To date there are selectively no FDA-approved CAR T-cell therapies for the treatment of solid tumors. FT825 is specifically designed incorporate to overcome these challenges in treating solid tumors, and incorporates seven novel synthetic controls of cell function: a 1XX CAR construct inserted directly into the TRAC locus that is armed with a novel human epidermal growth factor receptor 2 (HER2) binding domain designed to preferentially target tumor cells; a novel high-affinity 158V, non-cleavable CD16 (hnCD16) Fc receptor that has been modified to prevent its down-regulation and to enhance ADCC; a synthetic IL-7/IL-7 receptor fusion (IL-7RF), a potent cytokine complex that is intended to promote T-cell stemness; a synthetic CXCR2 receptor to promote cell trafficking; a synthetic TGFβ receptor to redirect immunosuppressive signals in the tumor microenvironment; the complete elimination of CD38 expression to promote persistence and function in high oxidative stress environments; and can deliver the complete disruption of TCR expression for the prevention of GvHD.

In preclinical studies of FT825 presented at the 2023 Society for Immunotherapy of Cancer (SITC) Annual Meeting, the product candidate's HER2 binding domain (H2CasMab-2) exhibited robust, dose-dependent cytolytic activity *in vitro* against both HER2-high and HER2-low cell lines from multiple mechanisms tumor types, and showed a highly selective and differentiated targeting profile *in vitro* against HER2-expressing cancer cell lines from healthy tissue in comparison to other HER2-directed agents such as trastuzumab (see figure below). FT825 also exhibited enhanced trafficking and resistance to TGFβ-induced suppression *in vitro* (see figure below). In addition to its CAR-mediated anti-tumor activity against HER2, co-activation of therapeutic importance to patients the product candidate's hnCD16 Fc receptor through combination with monoclonal antibody therapy showed enhanced anti-tumor activity.



In January 2024, and alongside our collaborator Ono Pharmaceutical (see "Our Partnership with Ono Pharmaceutical"), we announced the initiation of enrollment of a multi-center, Phase 1 clinical trial of FT825 for the treatment of cancer advanced solid tumors. The Phase 1 study is designed to evaluate the safety and autoimmune disease. We have activity of a deep pipeline single dose of product candidates currently under development with multiple clinical trials ongoing, including FT825 as monotherapy or in combination with mAb therapy monoclonal antibody therapy. The dose escalation and dose expansion portions of the Phase 1 study will evaluate safety, tolerability, and pharmacokinetics as well as anti-tumor activity by overall response rate, duration of response and disease control rate.

FT522: CAR NK Cell Program

FT522 is our first iPSC-derived CAR NK cell product candidate that incorporates our novel Alloimmune Defense Receptor (ADR) technology, which is designed to reduce or eliminate the need for administration of intense conditioning chemotherapy to

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patients receiving cellular immunotherapy. While approved autologous CAR T-cell therapies have demonstrated compelling efficacy in treating patients with relapsed / refractory hematologic malignancies, several key challenges limit its adoption and patient reach including the need to co-administer

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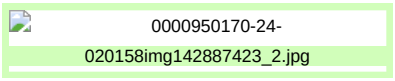
conditioning chemotherapy to patients. Conditioning chemotherapy induces toxicities, necessitates administration in large hospitals and treatment centers with intensive care units, and prevents effective combination with standard-of-care treatment regimens widely used in the community setting. Its use has also been associated with treatment-emergent secondary malignancies, such as myelodysplastic syndrome. In addition, the FDA recently announced an investigation into reports of secondary T-cell malignancies among patients receiving autologous CAR T-cell therapies and, as part of such investigation, the FDA is requiring that all commercially-approved BCMA-directed or CD19-directed autologous CAR T-cell therapies include a black box warning describing the risk of T-cell malignancies on each product's label.

FT522 incorporates five novel synthetic controls of cell function: a proprietary CAR that targets CD19; a novel high-affinity 158V, non-cleavable CD16 (hnCD16) Fc receptor that has been modified to prevent its down-regulation and to enhance ADCC in combination with a monoclonal antibody; an IL-15/IL-15 receptor fusion (IL-15RF), a potent cytokine complex that is intended to augment NK cell activity; the complete elimination of CD38 expression to promote multi-antigen recognition, binding, persistence and function in high oxidative stress environments; and a novel synthetic ADR targeting the cell surface receptor 4-1BB (CD137), a member of the tumor necrosis factor receptor superfamily that is upregulated on activated CD4+, CD8+, and regulatory T-cells as well as activated NK cells of the host immune system. In combination with monoclonal antibody therapy, these features of FT522 are designed to reduce or eliminate the need for administration of intense conditioning chemotherapy to patients, enable dual-antigen targeting of antigens expressed on B cells, and extend the functional persistence of FT522.

In preclinical studies, we showed that ADR-armed CAR NK cells selectively targeted and eliminated alloreactive immune cells in an in vitro co-culture assay with allogeneic peripheral blood mononuclear cells (see figure below); targeted and eliminated activated T-regulatory cells, overcoming a major suppressive mechanism associated with poor anti-tumor activity; and were potentiated through 4-1BB engagement, promoting NK cell expansion and persistence. In addition, in a disseminated Nalm6 leukemia model comprised of alloreactive T-cells and CD19+ tumor cells resistant to T-cell killing (MHC class 1-null), ADR-armed, CD19-targeted, iPSC-derived CAR NK cells exhibited uncompromised effector function in vivo compared to ADR-null, CD19-targeted, iPSC-derived CAR NK cells, suggesting that ADR-armed NK cells functionally persist, proliferate, and kill tumor cells while resisting rejection by alloreactive T-cells. These preclinical data suggest that FT522 has the potential to robustly deplete CD19+ B cells, evade host immune cell rejection, and drive clinical responses without administration of target cells. intense conditioning chemotherapy to patients.



B-cell Lymphoma

We are currently conducting a multi-center, Phase 1 clinical trial of FT522 to assess its safety, pharmacokinetics, and clinical activity in patients with relapsed / refractory BCL. The Phase 1 study includes two regimens: Regimen A, or the "conditioning" arm, which consists of 3 days of standard conditioning chemotherapy; 1 dose of rituximab; and 3 doses of FT522; and Regimen B, or the "no conditioning" arm, which consists of 1 dose of rituximab and 3 doses of FT522 without conditioning chemotherapy. Enrollment into Regimen A is ongoing at the first dose level of 300 million cells per dose and, upon clearance of dose-limiting toxicities at this first dose level, we intend to initiate enrollment into Regimen B at the first dose level of 300 million cells per dose. Each regimen may proceed with dose escalation independently. We believe we have the opportunity to establish clinical proof-of-concept for our ADR technology, and for our FT522 program without conditioning chemotherapy, early in dose escalation.

Autoimmune Diseases

We are also assessing the potential to expand our FT522 program into autoimmune diseases. While therapeutic strategies designed to deplete B cells, including treatment with CD20-targeted monoclonal antibody therapy, have been shown effective for

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induction and maintenance of remission in certain patients with autoimmune diseases, aberrant production of auto-antibodies by plasma cells is also an inherent characteristic of autoimmune diseases. Notably, recent findings suggest that long-lived plasma cells often accumulate later in the course of disease and are refractory to immunosuppressants and B-cell depletion therapies, leading to the persistent secretion of auto-antibodies despite B-cell targeted intervention strategies. We believe our FT522 program in combination with CD38-targeted monoclonal antibody therapy may be uniquely suited to address a broad range of autoimmune diseases through the potential reset of both CD19+ B-cell and CD38+ plasma-cell autoantibody-producing lineages.

FT576: CAR NK Cell Program for Multiple Myeloma

Multiple myeloma FT576 is a deadly form of blood cancer our iPSC-derived CAR NK cell product candidate that is characterized by uncontrolled growth of designed to target B-cell maturation antigen (BCMA) expressed on plasma cells, a type of immune cell that is found mainly in the bone

Options	
Outstanding at December 31, 2021	7,708,263
Outstanding at December 31, 2022	

marrow and is responsible for making and secreting antibodies to fight infection. While the underlying cause of multiple myeloma is unknown, abnormal plasma cells can accumulate in the bone marrow, inhibiting the body's normal production of red blood cells, platelets, and other white blood cells, and can form tumors in the bone that spread throughout the body.

There are approximately 100,000 patients suffering from multiple myeloma in the United States, with 35,000 new cases and nearly 13,000 deaths from the disease annually according to the American Cancer Society. Multiple myeloma occurs more commonly in men than in women, and predominantly affects the elderly with an average age of onset of approximately 66 years. For patients less than 70 years old with no comorbidities, autologous stem cell therapy is the preferred treatment option. For transplant ineligible patients, the current treatment paradigm for multiple myeloma begins with chemotherapy, proteasome inhibitors and immunomodulatory drugs. Several drugs that directly target plasma cells, including CD38-targeted mAb monoclonal antibody therapy, have also been approved for the treatment of multiple myeloma, and have been incorporated into a deadly form of blood cancer that is characterized by uncontrolled growth of abnormal plasma cells in the current treatment paradigm. bone marrow. In addition, autologous CAR T-cell therapies have shown significant promise efficacy in multiple myeloma, and the first two autologous CAR T-cell therapy therapies targeting B-cell maturation antigen (BCMA) expressed on plasma cells was BCMA have been approved by the FDA in 2021. The great majority of patients become refractory to FDA. Despite these drugs and/or relapse, advancements, multiple myeloma is rarely cured, creating a high unmet need for treatments for patients with relapsed / refractory patients. Multiple myeloma is rarely cured, with the majority of patients dying from the disease.

In August 2019, we We entered into a license agreement with the Max Delbrück Center for Molecular Medicine (MDC) under which we were granted certain exclusive rights to intellectual property covering novel humanized CAR constructs that uniquely and specifically bind BCMA. In data published by MDC scientists, anti-BCMA BCMA-targeted CAR T cells equipped T-cells armed with its unique humanized extracellular antigen-binding domains show showed higher affinity and greater specificity than other anti-BCMA BCMA-targeted antigen-binding domains. These differentiated properties conveyed both greater selectivity in recognizing target B plasma cells and more robust killing of target B plasma cells *in vitro*, including malignant B plasma cells with low expression levels of BCMA. Additionally, in *in vivo* proof-of-concept studies, MDC scientists demonstrated that anti-BCMA BCMA-targeted CAR T cells T-cells mediated anti-tumor activity in xenotransplant mouse models of multiple myeloma and of mature B-cell non-Hodgkin lymphoma, where BCMA surface expression is typically up to 4-fold lower as compared to mouse models of multiple myeloma.

We are clinically developing FT576, an investigational off-the-shelf, multiplexed-engineered, iPSC-derived CAR NK cell cancer immunotherapy derived from a clonal master iPSC line. FT576 incorporates four novel synthetic controls of cell function: a proprietary CAR that targets BCMA; a novel high-affinity 158V, non-cleavable CD16 (hnCD16) Fc receptor that has been modified to prevent its down-regulation and to enhance ADCC; an IL-15/IL-15 receptor fusion (IL-15RF), a potent cytokine complex that is intended to augment NK cell activity; and the complete elimination of CD38 expression to promote persistence and function in high oxidative stress environments. In combination with CD38-targeted mAb monoclonal antibody therapy, these features of FT576 are designed to avoid NK cell fratricide, enable dual-antigen targeting of BCMA and CD38 antigens expressed on plasma cells, and extend functional persistence, and mitigate the risk of rejection. persistence. In preclinical studies, FT576 demonstrated that the high-avidity binding of the its BCMA-targeted CAR construct enabled sustained tumor control against various multiple myeloma cell lines, including in long-term *in vivo* xenograft mouse models. Additionally, preclinical data published in November 2022 demonstrated that single-dose administration of FT576 controlled tumor growth

in vivo, with deeper and more sustained anti-tumor activity observed through multi-dose administration of FT576 as well as in combination with CD38-targeted mAb therapy (Cichocki et al. *Nature Communications*. 13, 7341, 2022). Multiple Myeloma

We are currently studying evaluating FT576 in an ongoing, multi-center, Phase 1 clinical trial designed to assess its safety, pharmacokinetics, and clinical activity in adult patients with relapsed / refractory multiple myeloma, and to determine the recommended Phase 2 dose and schedule, as monotherapy (Regimen A) and in combination with CD38-targeted mAb monoclonal antibody therapy to simultaneously target BCMA and CD38 antigens (Regimen B). At the 2022 American Society of Hematology (ASH) ASH Annual Meeting, we presented interim clinical data as of an October 7, 2022 data cutoff date for nine 9 patients with relapsed / refractory multiple myeloma treated with a single dose of FT576, including six patients in Regimen A and three patients in Regimen B. B treated in our ongoing Phase 1 study. Patients had were heavily pre-treated having received a median of 5 prior lines of therapy (range 3-10), including 6 of 9 patients (67%) that were refractory to last therapy. Each of the 9 patients received standard conditioning chemotherapy consisting of cyclophosphamide (Cy) at 300 mg/m2 m^2 and fludarabine (Flu) at 30 mg/m2 m^2 for three days prior followed by a single dose of FT576 ranging from 100 million cells to the initiation 300 million cells. As of each regimen. Patients were heavily pre-treated having had received a median of five prior lines of therapy (range 3-10), including six patients (67%) that were refractory to last therapy. an October 7, 2022 data cutoff date:

- *Safety Data Tolerability*. No dose-limiting toxicities (DLTs) were observed, and both regimens were well tolerated. Two patients (22%) experienced Grade 3 or greater FT576-related treatment-emergent adverse events (TEAEs), and all of which resolved. There were no FT576-related serious TEAEs. With respect to TEAEs of special interest, there were no events of any grade of cytokine release syndrome (CRS), immune effector cell-associated neurotoxicity syndrome (ICANS), or GvHD, were observed. Both regimens were well tolerated.

Granted	848,457(94,178)
Exercised	80)
Cancelled	14)
Outstanding at December 31, 2022	7,267,226
Options vested and expected to vest at December 31, 2022	7,267,226
Options exercisable at December 31, 2022	5,727,203

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Two patients (22%) experienced Grade 3 or greater FT576-related adverse events (AEs), with one patient having Grade 3 diarrhea and one

patient having two episodes of Grades 3 through 4 neutropenia and three episodes of Grade 3 anemia, all of which resolved. There were no serious AEs related to FT576. GvHD. There were no study discontinuations or deaths due to treatment-emergent AEs (TEAEs). TEAEs.

- *Regimen A Activity Activity.* . Six patients were treated with a single dose of FT576 as monotherapy in the first dose cohort at 100 million cells (n=3) and the second dose cohort at 300 million cells (n=3). In the second dose cohort, one patient, who had received five 5 prior lines of therapy, was triple-refractory to an immunomodulatory drug, a proteasome inhibitor, and anti-CD38 mAb monoclonal antibody therapy, and was refractory to last therapy (pomalidomide, daratumumab and dexamethasone), achieved a very good partial response (VGPR) with the other two patients showing stable disease.

Outstanding at December 31, 2023

Options vested and expected to vest at December 31, 2023

Options exercisable at December 31, 2023

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Further evidence of FT576 activity was observed in the second dose cohort, with two patients for whom serum BCMA levels were evaluable showing a substantial treatment-induced decrease in soluble BCMA.

- *Regimen B Activity Activity.* . Three patients were treated with a single dose of FT576 in combination with a CD38-targeted mAb monoclonal antibody therapy in the first dose cohort at 100 million cells, with one patient achieving a partial response (PR) and one patient achieving a minor response (MR). All three patients showed a substantial treatment-induced decrease in soluble BCMA.

We have initiated enrollment of two-dose escalation cohorts at 300 million cells per dose in both regimens, and we plan to initiate enrollment of three-dose escalation cohorts at 300 million cells per dose in both regimens and continue dose escalation.

FT522: CAR NK Cell Program for B-cell Lymphoma and Autoimmune Disorders

Non-Hodgkin lymphoma (NHL) is a type of blood cancer that originates in the body's lymphatic system. In NHL, white blood cells, called lymphocytes, grow abnormally and can form tumors throughout the body. The most common subtype of NHL is B-cell lymphoma, which represents over 85% of all newly-diagnosed NHL cases per year. B-cell lymphoma can be rapidly growing, or aggressive, such as diffuse large B-cell lymphomas, or it can be slow growing, or indolent, such as follicular lymphoma.

There are over 80,000 new cases of NHL diagnosed per year in the United States, with over 20,000 deaths from the disease annually, according to the American Cancer Society. Patients with newly-diagnosed B-cell lymphoma are generally treated with chemotherapy plus a CD20-targeted mAb, with the R-CHOP chemotherapy combination (rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone) established as standard of care for newly-diagnosed diffuse large B-cell lymphoma patients. While the frontline approach of chemotherapy plus a CD20-targeted mAb is highly effective for many NHL patients, most patients suffer from disease that is refractory to initial treatment or recurrent after an initial response. Each year there are over 20,000 patients that require second-line treatment and nearly 10,000 patients that require third-line or later lines of therapy. For patients with refractory or relapsed disease, prognosis worsens with each subsequent line of therapy.

Autologous CD19-targeted CAR T-cell therapy has been highly successful in treating patients with relapsed / refractory B-cell lymphoma. While the autologous approach has demonstrated compelling efficacy in many patients, several key challenges limit its adoption and reach including the need to co-administer intense chemotherapy conditioning, to hospitalize patients for treatment and monitoring, and to deliver bridging therapy during product manufacture. In registrational trials of CD19-targeted CAR T-cell therapy, up to 31% of patients on an intent-to-treat basis did not receive therapy primarily due to interval complications from the underlying disease prior to delivery of therapy or failure to manufacture therapy. Additionally, patients with relapsed / refractory disease can have a T-cell compartment that is damaged or weakened, which may impair product manufacture, viability, potency, and/or response. The manufacture and delivery of autologous CAR T-cell therapy is logistically complex and costly and, as a result, its availability is limited to select specialized centers.

We are preclinically developing FT522, an off-the-shelf, multiplexed-engineered, iPSC-derived CAR NK cell cancer immunotherapy derived from a clonal master iPSC line. FT522 incorporates five novel synthetic controls of cell function: a proprietary CAR that targets CD19; a novel high-affinity 158V, non-cleavable CD16 (hnCD16) Fc receptor that has been modified to prevent its down-regulation and to enhance ADCC; an IL-15/IL-15 receptor fusion (IL-15RF), a potent cytokine complex that is intended to augment NK cell activity; the complete elimination of CD38 expression to promote persistence and function in high oxidative stress environments; and a novel alloimmune defense receptor (ADR) that targets the cell surface receptor 4-1BB (CD137), a member of the tumor necrosis factor receptor superfamily that is upregulated on activated CD4+, CD8+, and regulatory T cells as well as activated NK cells of the host immune system. In combination with CD20-targeted mAb therapy, these features of FT522 are designed to enable dual-antigen targeting of CD19 and CD20 antigens expressed on B cells, extend functional persistence, and mitigate the risk of rejection.

We are currently conducting IND-enabling activities for FT522, and plan to submit an IND application to the FDA in 2023 to enable the initiation of first-in-human clinical investigation for the treatment of relapsed / refractory B-cell lymphoma. Preclinical proof-of-concept data for FT522 presented at the 2022 ASH Annual Meeting showed that, in an *in vitro* co-culture assay with allogeneic peripheral blood mononuclear cells (allo PBMCs), ADR-armed, CD19-targeted, iPSC-derived CAR NK cells expanded, persisted, and selectively eliminated 4-1BB+ allo PBMCs in contrast to ADR-null, CD19-

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targeted, iPSC-derived CAR NK cells,

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which were depleted. In addition, in a disseminated Nalm6 leukemia model comprised of allo-reactive T cells and tumor cells resistant to T-cell killing (MHC class 1-null), ADR-armed, CD19-targeted, iPSC-derived CAR NK cells exhibited uncompromised effector function *in vivo* compared to ADR-null, CD19-targeted, iPSC-derived CAR NK cells, suggesting that ADR-armed NK cells functionally persist, proliferate, and durably kill tumor cells while resisting rejection by allo-reactive T cells.

In addition to our plans for the clinical investigation of FT522 in relapsed / refractory B-cell lymphoma, we are assessing in preclinical studies the potential to expand our FT522 program beyond oncology into autoimmunity. Autoimmune diseases are conditions in which the body's immune system mistakenly attacks the body's own organs and tissues. The role of B cells in autoimmune diseases involves different cellular functions, including autoantigen presentation, autoreactive T-cell activation, and autoantibody production. Therapeutic strategies designed to deplete B cells, including treatment with CD20-targeted mAb therapy, have been shown effective for induction and maintenance of remission in patients with certain autoimmune diseases. In addition, autologous CD19-targeted CAR T-cell therapy has been shown to induce durable remissions in patients with severe, refractory systemic lupus erythematosus. Aberrant production of autoantibodies by long-lived plasma cells is also an inherent characteristic of autoimmune diseases. Notably, recent findings suggest that long-lived plasma cells often accumulate later in the course of disease and are refractory to immunosuppressants and B-cell depletion therapies, leading to the persistent secretion of autoantibodies despite B-cell targeted intervention strategies. We believe the novel synthetic controls of FT522, in combination with CD38-targeted mAb therapy, may be uniquely suited to address a broad range of autoimmune diseases and disorders by resetting both of these autoantibody-producing lineages through the dual-targeting of CD19-and CD20-expressing B cells and CD38-expressing plasma cells, leading to more complete removal of autoantibodies and improved clinical outcomes.

FT819: CAR T-cell Program for B-cell Lymphoma and Chronic Lymphocytic Leukemia

In addition to our development of iPSC-derived CAR NK cell product candidates, we are also developing CAR T-cell product candidates derived from clonal master iPSC lines as off-the-shelf cancer immunotherapies for the treatment of hematologic malignancies and solid tumors. In support of our development of iPSC-derived CAR T-cell product candidates, we are conducting a multi-year research partnership with Memorial Sloan Kettering Cancer Center (MSKCC) that is being led by Dr. Michel Sadelain, Director of the Center for Cell Engineering and the Stephen and Barbara Friedman Chair at Memorial Sloan Kettering Cancer Center. In addition, we have exclusively licensed from MSKCC foundational intellectual property covering iPSC-derived cellular immunotherapy, including T cells and NK cells derived from iPSCs engineered with CARs, for human therapeutic use. We have also licensed from MSKCC intellectual property covering compositions of novel CAR constructs, including the use of a novel 1XX co-stimulatory domain, and of genetically engineered CAR T cells, including methods of making these cells using CRISPR for certain targeted gene modifications. Embodiments of this additional intellectual property include preclinical data published by Dr. Sadelain demonstrating that directing a CD19-specific CAR to the TRAC locus resulted in uniform CAR expression in human peripheral blood T cells, enhanced T-cell potency, and delayed effector T-cell differentiation and exhaustion (Eyquem et al. *Nature*. 543, 113–117, 2017), and that CAR T cells utilizing a novel 1XX CAR signaling domain exhibited enhanced antitumor activity, persistence and long-term cytotoxicity as well as a decrease in T-cell exhaustion (Feucht et al. *Nature Medicine*. 25, 82–88, 2019).

We are clinically developing FT819, an investigational off-the-shelf, iPSC-derived CAR T cell cancer immunotherapy derived from a clonal master iPSC line. FT819 incorporates two novel synthetic controls of cell function: a novel 1XX CAR construct inserted directly into the TRAC locus that targets CD19; and the complete disruption of TCR expression for the prevention of GvHD, a potentially life-threatening complication associated with allogeneic T-cell therapy. Together, these features of FT819 are designed to induce antigen-specific cytotoxicity, enhance CAR activity through TRAC-regulated expression, and completely eliminate TCR expression to mitigate GvHD. In preclinical studies, we have shown that iPSC-derived TCR-CAR+ CAR T cells targeting CD19:

- displayed antigen-specific anti-tumor potency *in vitro*, including cytokine release and targeted cellular cytotoxicity, comparable to peripheral blood CD19-specific CAR T-cells;
- did not respond or proliferate against HLA-mismatched (CD19-) peripheral blood mononuclear cells as targets in a mixed lymphocyte reacti indicating the risk of GvHD is alleviated;
- controlled tumor progression *in vivo* comparable to peripheral blood CD19-specific CAR T cells in a preclinical mouse model of acute lymphoblastic leukemia; and
- enhanced tumor clearance and durable control of leukemia *in vivo*, as compared to primary CAR19 T cells, in a xenograft mouse model of disseminated lymphoblastic leukemia.

Additional preclinical data published in August 2022 showed the generation of iPSC-derived TCR-CAR+ CD8αβ T cells, which were able to repeatedly lyse tumor cells *in vitro* and durably control leukemia *in vivo*, with persistence in the bone marrow, spleen, and blood, in a systemic NALM6 leukemia model (Sjoukje et al. *Nature Biomedical Engineering*. 6, 1284–1297, 2022).

We are currently studying FT819 in an ongoing, multi-center Phase 1 clinical trial designed to assess its safety and clinical activity in adult

Number of Restricted Stock Units	
Outstanding at December 31, 2021	4,008,832
Outstanding at December 31, 2022	3,211,122

patients with relapsed / refractory B-cell malignancies, including B-cell lymphoma and chronic lymphocytic

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leukemia, and to determine the recommended Phase 2 dose and schedule, in three treatment regimens: single dose of FT819 (Regimen A); single dose of FT819 with IL-2 cytokine support (Regimen A1); and three fractionated doses of FT819 on Days 1, 3, and 5 (Regimen B). At the 2022 ASH Annual Meeting, we presented interim clinical data as of a September 8, 2022 data cutoff date for 10 patients with aggressive large B-cell lymphoma treated with FT819, including eight patients in Regimen A and two patients in Regimen B (see Table 1). Patients had received standard conditioning chemotherapy consisting of cyclophosphamide (Cy) at 500 mg/m2 and fludarabine (Flu) at 30 mg/m2 for three days prior to the initiation of each regimen. Patients were heavily pre-treated having had received a median of four prior lines of therapy (range 3-7), including 7 of 10 patients (70%) having previously received autologous CD19-targeted CAR T-cell therapy.

- *Regimen A Activity*. Of the eight patients with aggressive large B-cell lymphoma (median of 4.5 prior lines of therapy [range 3-7]) treated with a single dose of FT819 ranging from 90 million cells to 360 million cells, one of two patients naïve to CAR T-cell therapy achieved an objective response at Day 30, which was a complete response in a patient with diffuse large B-cell lymphoma previously treated with five prior lines of therapy; and two of six patients previously treated with CAR T-cell therapy achieved an objective response at Day 30, which included a complete response in a patient with diffuse large B-cell lymphoma previously treated with seven prior lines of therapy who did not respond to autologous CD19-targeted CAR T-cell therapy.
- *Regimen B Activity*. Two patients with aggressive large B-cell lymphoma (each of whom received three prior lines of therapy) treated with three fractionated doses at 30 million cells per dose did not respond to therapy at Day 30.

Table 1: Aggressive Large B-cell Lymphoma [1,2,3]

FT819 Regimen A: Single Dose (n=8)						
	CAR T-cell Therapy Naïve			Prior CAR T-cell Therapy		
Cells	90M	180M	360M	90M	180M	360M
N	1	n/a	1	4	1	1
OR / CR	0 / 0	n/a	1 / 1	2 / 1	0 / 0	0 / 0

FT819 Regimen B: Three Fractionated Doses (n=2)		
	CAR T-cell Therapy Naïve	Prior CAR T-cell Therapy
Cells / Dose	30M	30M
N	1	1
OR / CR	0 / 0	0 / 0

OR = objective response; **CR**= complete response; **M** = million

[1] As of data cutoff date of September 8, 2022

[2] Includes diffuse large B-cell lymphoma (n=8) and high-grade B-cell lymphoma (n=2)

[3] Day 30 protocol-defined response assessment per Lugano 2014 criteria

Five additional patients with relapsed / refractory B-cell lymphoma had been treated with FT819 as of the September 8, 2022 data cutoff date: one patient with Grade 3a follicular lymphoma (with 5 prior lines of therapy, including CAR T-cell therapy) treated in Regimen A with a single dose of FT819 at 180 million cells achieved a complete response at Day 30; and four patients with Richter's Transformation (median of 5.5 prior lines of therapy [range 2-9]) did not respond to therapy at Day 30.

No DLTs, and no Grade 3 or greater FT819-related AEs or serious AEs, were observed. Of the 15 patients treated in Regimens A and B, three patients (20%) experienced Grade 2 CRS characterized by fever, hypotension, and hypoxia, and which resolved with single-dose tocilizumab and supportive care. No TEAEs of any grade of ICANS or GvHD were reported by investigators. The FT819 treatment regimen was well tolerated. There were no study discontinuations or deaths due to TEAEs other than one patient with stable disease who died on Day 38 due to sepsis not considered related to FT819 by the study investigator.

Dose escalation is currently ongoing in Regimen A as a single dose of FT819 at 360 million cells and in Regimen B with three fractionated doses at 60 million cells per dose. The Company has also amended the FT819 FT576 study protocol to allow for the use of bendamustine at 90 mg/m2 m^2 for two days as an alternative to Cy / Flu conditioning chemotherapy. Dose escalation in the multi-center, Phase 1 clinical trial of FT576 is currently ongoing, with three-dose cohorts being assessed in both Regimens A and B at up to 2.5 billion cells per dose. We currently do not plan to assess FT576 at a dose level above 2.5 billion cells per dose, and any further clinical development of FT576 in patients with relapsed / refractory multiple myeloma will be determined upon completion of the dose escalation at this current dose level.

FT825: CAR T-cell Program for Solid Tumors

Although autologous CAR T-cell therapies approved by the FDA have shown significant efficacy in treating hematologic malignancies, its wider application to solid tumors has been hampered by tumor-associated antigen heterogeneity, inefficient CAR T-cell trafficking to the tumor, and

Granted 8

Vested (6,265,175)

Cancelled (731,132)

Outstanding at December 31, 2022 5,862,743

Restricted stock units expected to vest at December 31, 2022 4,065,114

Outstanding at December 31, 2023

Restricted stock units expected to vest at December 31, 2023

As of Dec 2020, 2022, t outstanding r performance- million and $ be recognize years, 3.2 ye

immunosuppression inherent to the tumor microenvironment. We are researching and preclinically developing multiplexed-engineered, iPSC-derived CAR T-cell product candidates, which are specifically designed to address these challenges and enable the safe and effective treatment of solid tumors as monotherapy and in combination with mAb therapy.

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Autoimmune Diseases

We are preclinically developing FT825, a multiplexed-engineered, iPSC-derived, CAR T-cell product candidate targeting human epidermal growth factor receptor 2 (HER2)-expressing solid tumors, under also assessing the potential to expand our collaboration with Ono (see "Our Partnership with Ono Pharmaceutical"). HER2, also known FT576 program into autoimmunity. Auto-antibody-secreting plasma cells are increasingly recognized as Human Epidermal Growth Factor Receptor 2, is a receptor tyrosine kinase that is overexpressed on many solid tumors, essential drivers of pathophysiology in certain autoimmune diseases, such as breast, gastric, bladder, and lung cancers. FT825 incorporates seven novel synthetic controls of cell function: a novel 1XX CAR construct inserted directly into the TRAC locus myasthenia gravis. Existing myasthenia gravis therapies do not adequately or specifically target long-lived plasma cells that is armed with a differentiated HER2 binding domain; a novel high-affinity 158V, non-cleavable CD16 (hnCD16) Fc receptor that has been modified to prevent its down-regulation and to enhance ADCC and to overcome challenges associated with tumor heterogeneity; a synthetic IL-7/IL-7 receptor fusion (IL-7RF), a potent cytokine complex that is intended to promote T-cell stemness; a synthetic CXCR2 receptor to promote cell trafficking; a synthetic TGFβ receptor to redirect immunosuppressive signals reside in dedicated survival niches in the tumor microenvironment; bone marrow or inflamed tissue. These long-lived plasma cells are unresponsive to immunosuppressive and B-cell therapies. We believe our FT576 program, which has the complete elimination potential to target BCMA expressed on the surface of CD38 expression to promote persistence and function in high oxidative stress environments; and the complete disruption of TCR expression for the prevention of GvHD, a potentially life-threatening complication associated with allogeneic T-cell therapy.

In preclinical studies of FT825 presented at the 2022 Society for Immunotherapy of Cancer (SITC) Annual Meeting, the product candidate's HER2 binding domain showed a highly selective and differentiated targeting profile including in comparison to other HER2-directed agents, exhibited robust dose-dependent cytolytic activity against both HER2-high and HER2-low cell lines from multiple tumor types, demonstrated limited activity against HER2-expressing cell lines from healthy tissue, and exhibited enhanced trafficking and migration properties in vitro and in vivo. In addition to its CAR-mediated anti-tumor activity against HER2, co-activation of the product candidate's HER2-targeted CAR and hnCD16 Fc receptor through combination with mAb therapy showed enhanced anti-tumor activity in preclinical models.

Under our collaboration with Ono, we are currently conducting IND-enabling activities for FT825, and plan to submit long-lived plasma cells, may represent an IND application to the FDA in 2023 to enable the initiation of first-in-human clinical investigation innovative therapeutic strategy for the treatment of certain solid tumors. autoimmune diseases.

Discontinued Product Candidates

Janssen Collaboration. On January 3, 2023, we received notice of termination from During 2022, Janssen Biotech, Inc. (Janssen) of our collaboration and option agreement dated April 2, 2020 by and between the parties (the Janssen Agreement), pursuant to which the companies had agreed to collaborate to develop iPSC-derived CAR NK- and CAR T-cell product candidates for the treatment of cancer. During 2022, Janssen exercised a commercial option for two collaboration candidates: an iPSC-derived CAR-targeted CAR NK cell product candidate for the treatment of B-cell lymphoma, for which the FDA allowed an IND application in December 2022; and an iPSC-derived CAR-targeted CAR NK cell product candidate for the treatment of multiple myeloma, for which the companies were preparing to submit an IND application to the FDA in early 2023. In addition, the companies were researching and preclinically developing two iPSC-derived CAR-targeted CAR T-cell programs for the treatment of solid tumors. On January 3, 2023, we received notice of termination from Janssen of our collaboration and option agreement dated April 2, 2020 by and between the parties (the Janssen Agreement), pursuant to which the companies had agreed to collaborate to develop iPSC-derived CAR NK cell and CAR T-cell product candidates for the treatment of cancer. The termination will be was finalized on April 3, 2023 and, during the first quarter of 2023, we will completed wind down our activities with Janssen, including discontinuing development of all collaboration products. Under the terms of the Janssen Agreement, in connection with the termination, (i) all licenses and other rights granted to either party pursuant to the Janssen Agreement will terminate, subject to limited exceptions set forth in the Janssen Agreement; (ii) both parties will wind down any development, commercialization and manufacturing activities under the Janssen Agreement; (iii) neither party will have any right to continue to develop, manufacture or commercialize any collaboration candidate or collaboration product or use the other party's materials; and (iv) neither party is restricted from independently developing, manufacturing, or commercializing any product, including any products directed to the same antigens as those of any collaboration candidate or collaboration product.

Internal Programs. On January 5, 2023, we announced the completion of a strategic review of our NK cell programs and our election to focus on advancing our most innovative and differentiated product candidates, which have a multiplexed-engineered cellular framework of novel synthetic controls designed to promote multi-antigen targeting, increase potency, extend functional persistence, and enable patient dosing with reduced conditioning chemotherapy. As a result of our NK cell program prioritization, our FT516, FT596, FT538, and FT536 NK cell programs are being were discontinued.

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Workforce Reduction. As a result of the termination of the Janssen collaboration and the NK cell program prioritization, during the first quarter of 2023 we are reducing reduced our workforce to approximately 220 employees. We expect that we will incur incurred charges of approximately $12 million to $16 million $12.9 million for severance and other employee termination-related costs in during the first quarter of 2023. The restructuring is expected to extend our cash runway into the second half of 2025. year ended December 31, 2023.

Our Partnership with Ono Pharmaceutical

Under a collaboration and option agreement with Ono Pharmaceutical Co. Ltd. (Ono) entered into in September 2018 and amended in June 2022 (the Ono Agreement), we are conducting research and preclinical development of off-the-shelf, iPSC-derived CAR-targeted effector cells CAR NK cell and CAR T-cell product candidates for the treatment of solid tumors.

In November 2022, we announced that Ono had exercised its preclinical option to FT825/ FT825 / ONO-8250, a an off-the-shelf, multiplexed-engineered, iPSC-derived CAR T-cell product candidate targeting HER2-expressing solid

tumors (also referred to as Candidate 2 below), and that we exercised our preclinical option to co-develop and co-commercialize FT825/ FT825 / ONO-8250 in the United States and Europe under a joint arrangement with Ono. As a result, we are owed received an option exercise fee of $12.5 million from

Ono. The companies are currently conducting IND-enabling activities for FT825/ONO-8250, and plan to submit an IND application to the FDA in 2023 to enable In January 2024, we announced the initiation of enrollment of a first-in-human Phase 1 clinical investigation. trial of FT825 / ONO-8250 for the treatment of advanced solid tumors.

The companies are also currently conducting preclinical development of a second off-the-shelf, iPSC-derived CAR-targeted effector cell product candidate for the treatment of solid tumors (referred to as Candidate 3 below) under the Ono Agreement.

Under the original Ono Agreement entered into in September 2018, we and Ono intended to research and preclinically develop two iPSC-derived CAR T-cell product candidates, one of which was designated to target an antigen expressed on certain lymphoblastic leukemias (Candidate 1) and the second of which was designated to target an antigen expressed on certain solid tumors (Candidate 2) (each a Candidate and, collectively, the Candidates). We granted to Ono, during a specified period of time, a preclinical option to obtain an exclusive license under certain intellectual property rights to develop and commercialize: (a) Candidate 1 in Asia, where we retained rights for development and commercialization in all other territories of the world; and (b) Candidate 2 in all territories of the world, where we retained rights to co-develop and co-commercialize Candidate 2 in the United States and Europe under a joint arrangement with Ono under which we are eligible to share at least 50% of the profits and losses. We maintained worldwide rights of manufacture for each Candidate. For each Candidate, the preclinical option expired upon the earliest of: (a) the achievement of the pre-defined preclinical milestone under the joint development plan; (b) termination by Ono of research and development activities for the Candidate; and (c) the date that is the later of (i) four years after the effective date, and (ii) completion of all applicable activities contemplated under the joint development plan. Ono paid us an upfront, non-refundable and non-creditable payment of $10.0 million in connection with entering into the Ono Agreement. Additionally, as consideration for our conduct of research and preclinical development under a joint development plan, Ono agreed to pay us annual research and development fees set forth in the annual budget included in the joint development plan, which fees were estimated to be $20.0 million in aggregate over the course of the joint development plan.

In December 2020, we entered into a letter agreement with Ono pursuant to which Ono delivered to us proprietary antigen binding domains targeting an antigen expressed on certain solid tumors for incorporation into Candidate 2 and paid us a milestone fee of $10.0 million for further research and development of Candidate 2. In addition, Ono terminated all further research and development with respect to Candidate 1, and we retained all rights to research, develop and commercialize Candidate 1 throughout the world without any obligation to Ono.

In June 2022, we entered into an amendment with Ono to the Ono Agreement (the 2022 Ono Amendment). Pursuant to the 2022 Ono Amendment, the companies agreed to designate an additional antigen expressed on certain solid tumors for research and preclinical development, and Ono agreed to contribute to us proprietary antigen binding domains targeting such additional solid tumor antigen (Candidate 3). In addition, for both Candidate 2 and Candidate 3, the companies expanded the scope of the collaboration to include the research and development of iPSC-derived CAR

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Candidate 2, we granted to Ono, during a specified period of time, a preclinical option to obtain an exclusive license under certain intellectual property rights, subject to payment of an option exercise fee to us by Ono, to develop and commercialize Candidate 3 in all territories of the world, where we retained rights to co-develop and co-commercialize Candidate 3 in the United States and Europe under a joint arrangement with Ono under which we are eligible to share at least 50% of the profits and losses. We maintained worldwide rights of manufacture for Candidate 3. The preclinical option expires upon the earlier of: (a) September 30, 2024, or (b) the achievement of the pre-defined preclinical milestone under the joint development plan for Candidate 3. Subject to payment to us of an extension fee by Ono, Ono may choose to defer its decision to exercise the preclinical option until no later than June 2026. Ono agreed to pay us annual research and development fees set forth in the annual budget included in the joint development plan for Candidate 3.

Under the terms of the Ono Agreement (as amended by the 2022 Ono Amendment), for Candidate 2 and for Candidate 3 (subject to exercise by Ono of its preclinical option to Candidate 3), we are eligible to receive additional payments upon the achievement of certain clinical, regulatory and commercial milestones (the Ono Milestones) with respect to each Candidate in an amount up to $843.0 million in aggregate, with the applicable milestone payments for the United States and Europe subject to reduction by 50% if we elect to co-develop and co-commercialize the Candidate in the United States and Europe as described above. In addition, in those territories where Ono has exclusive rights of commercialization, we are eligible to receive tiered royalties (Royalties) ranging from the mid-single digits to the low-double digits based on annual net sales by Ono for each Candidate in such territories, with such royalties the Royalties subject to certain reductions.

On November 30, 2023, we entered into an amendment with Ono to the Ono Agreement (the 2023 Ono Amendment). Under the 2023 Ono Amendment, aggregate estimated research and development fees have been increased by approximately $1.4 million, for a total estimated $30.7 million in aggregate research and development fees over the course of the joint development plan.

The Ono Agreement will terminate with respect to a Candidate if Ono does not exercise its option for a Candidate within the option period, or in its entirety if Ono does not exercise any of its options for the Candidates within their respective option periods. In addition, either party may terminate the Ono Agreement in the event of breach, insolvency or patent challenges by the other party; provided, that Ono may terminate the Ono Agreement in its sole discretion (x) on a Candidate-by-Candidate basis at any time after the second anniversary of the effective date of the Ono Agreement or (y) on a Candidate-by-Candidate or country-by-country basis at any

time after the expiration of the option period, subject to certain limitations. The Ono Agreement will expire on a Candidate-by-Candidate and country-by-country basis upon the expiration of the applicable royalty term, or in its entirety upon the expiration of all applicable payment obligations under the agreement.

Our Intellectual Property

Overview

We seek to protect our product candidates and our cell programming technology through a variety of methods, including seeking and maintaining patents intended to cover our products and compositions, their methods of use and processes for their manufacture, our platform technologies and any other inventions that are commercially important to the development of our business. We seek to obtain domestic and international patent protection and, in addition to filing and prosecuting patent applications in the United States, we typically file counterpart patent applications in additional countries where we believe such foreign filing is likely to be beneficial, including Europe, Japan, Canada, Australia and China. We continually assess and refine our intellectual property strategy in order to best fortify our position, and file additional patent applications when our intellectual property strategy warrants such filings. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position. We have entered into exclusive license agreements with various academic and research institutions to obtain the rights to use certain patents for the development and commercialization of our product candidates.

As of February 18, 2023 February 15, 2024, our intellectual property portfolio is composed of over 450 issued patents and 150 patent applications that we license from academic and research institutions, and over 400 450 issued patents or pending patent applications that we own. These patents and patent applications generally provide us with the rights to develop our product candidates in the United States and worldwide. This

portfolio covers compositions of programmed cellular immunotherapies, our cell programming approach for enhancing the therapeutic function of cells *ex vivo*, and our platform for industrial-scale iPSC generation and engineering. We believe that we have a significant intellectual property position and substantial know-how relating to the programming of hematopoietic and immune cells and to the derivation, genetic engineering, and differentiation of iPSCs.

We cannot be sure that patents will be granted with respect to any of our owned or licensed pending patent applications or with respect to any patent applications we may own or license in the future, nor can we be sure that any of our existing patents or any patents we may own or license in the future will be useful in protecting our technology. Please see "Risk Factors—Risks Related to Our Intellectual Property" for additional information on the risks associated with our intellectual property strategy and portfolio.

Intellectual Property Relating to iPSC Technology and Platform

As of February 18, 2023 February 15, 2024, we own over 25 patent families directed to programming the fate of somatic cells *ex vivo*, including patent applications pending in the U.S. and internationally related to our platform for industrial-scale iPSC generation and applications related to differentiation of iPSCs into specialized cells with therapeutic potential. These patent applications cover our proprietary small molecule-enhanced iPSC platform, including novel reprogramming factors and methods of reprogramming to obtain iPSCs. Our intellectual property portfolio also includes gene editing compositions and methods of genetic engineering, as well as methods of directing the fate of cells to obtain homogenous cell populations in the hematopoietic lineage, including $CD34^+$ cells, T cells T-cells and NK cells. Our proprietary intellectual property enables highly-efficient iPSC derivation, selection, engineering, and clonal expansion while maintaining genomic stability. Any U.S. patents issued from these patent applications are expected to have statutory expiration dates ranging from 2031 to 2043.

Additionally, we have licensed from the Whitehead Institute for Biomedical Research a portfolio of four patent families including issued patents and pending applications broadly applicable to the reprogramming of somatic cells. Our license is exclusive in commercial fields, including for drug discovery and therapeutic purposes. This portfolio covers the generation of human iPSCs from somatic cells and, as of February 18, 2023 February 15, 2024, includes 17 21 issued U.S. patents (including U.S. Patents 8,071,369, 7,682,828 and 9,497,943) claiming compositions used in the reprogramming of mammalian somatic cells to a less differentiated state (including to a pluripotent state), and methods of making a cell more susceptible to reprogramming. Specifically, the portfolio includes a composition of matter patent issued in the United States covering a cellular composition comprising a somatic cell having an exogenous nucleic acid that encodes an OCT4 protein. OCT4 is the key pluripotency gene most commonly required for the generation of iPSCs. These issued patents and any U.S. patents that may issue from these pending patent applications are expected to have statutory expiration dates ranging from 2024 to 2029.

We also have exclusive licenses from The Scripps Research Institute to a portfolio of seven patent families relating to compositions and methods for reprogramming mammalian somatic cells, which covers non-genetic and viral-free reprogramming mechanisms, including the use of various small molecule classes and compounds and the introduction of cell-penetrating proteins to reprogram mammalian somatic cells. This portfolio includes issued U.S. patents (including U.S. Patents 8,044,201 and 8,691,573) that provide composition of matter protection for a class of small molecules, including thiazovivin, that is critical for inducing the generation, and maintaining the pluripotency, of iPSCs, and compositions and methods of using the small molecule. Any issued U.S.

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patents and any U.S. patents that may issue from patent applications pending in this portfolio are expected to have statutory expiration dates ranging from 2026 to 2031.

We also have exclusively licensed from the J. David Gladstone Institutes (Gladstone) intellectual property covering the generation of iPSCs using CRISPR-mediated gene activation. This approach for inducing pluripotency uses CRISPR to directly target

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a specific location of the genome and activate endogenous gene expression, and does not rely on established methods of cellular reprogramming that require the transduction of multiple transcription factors. Any U.S. patents that may issue from patent applications pending in the U.S. and internationally in this portfolio are expected to have a statutory expiration date in 2038.

We also have licensed exclusive rights to five families of patent applications from the University of Minnesota. As of February 18, 2023 February 15, 2024 this portfolio includes over 70 80 issued patents or pending patent applications in the United States and foreign jurisdictions directed to

compositions of NK cells, including adaptive memory NK cells and genetically-engineered NK cells, and therapeutic strategies for the treatment of cancer using these NK cells. These applications also describe methods of enhancing NK cell cytotoxicity by genetically engineering the CD16 Fc receptor in immune cells, including iPSC-derived NK cells, and describe methods of increasing NK cell tumor specificity and cytotoxicity by incorporating CARs on NK cells. Any U.S. patents that may issue from patent applications pending in this portfolio are expected to have statutory expiration dates between 2035 and 2038.

We also have exclusively licensed from The Memorial Sloan-Kettering Cancer Center (MSK) MSKCC intellectual property covering the production and composition of iPSC-derived T cells T-cells and their use in cellular immunotherapy, and have a license from MSK MSKCC to two patent families covering novel CAR constructs as well as off-the-shelf CAR T cells, T-cells, including the use of CRISPR and other innovative technologies for their production. Collectively, this portfolio covers compositions of CAR constructs, compositions of T cells T-cells and NK cells derived from pluripotent cells which are engineered with CARs, methods of engineering pluripotent cell lines, methods of deriving CAR-T cells CAR T-cells from CAR expressing pluripotent stem cells, and methods of using CRISPR for producing off-the-shelf T-cell immunotherapies. Any U.S. patents that may issue from patent applications pending in this portfolio are expected to have statutory expiration dates between 2034 and 2038.

In addition, we have licensed exclusive rights from the Max Delbruck Center for Molecular Medicine (MDC) to intellectual property directed to novel humanized antibody fragments, antigen-binding domains and CAR constructs that uniquely target and specifically bind B-cell Maturation Antigen (BCMA). BCMA. Under the license agreement, we are granted an exclusive license for use in allogeneic engineered pluripotent stem cells. Any patents issuing from patent applications pending in the U.S. and internationally in this portfolio are expected to have statutory expiration dates between 2033 and 2037.

We have also licensed exclusive rights from the Dana-Farber Cancer Institute (DFCI) to certain intellectual property covering novel antibody fragments that uniquely and specifically bind the alpha-3 domain of MICA/B. We are granted exclusive worldwide rights for use in iPSC-derived cellular therapeutics for the treatment of human disease under the license agreement. Any patents that may issue from patent applications pending in this portfolio are expected to have statutory expiration dates in 2038.

Additionally, we have licensed exclusive rights from BCM to intellectual property covering the composition and use of a novel ADR that selectively targets activated T-cells to protect engineered allogeneic cell products expressing the ADR from elimination in the host immune system. Under the license agreement with BCM, we are granted exclusive worldwide rights to use ADR in the field of iPSC-derived cell products, including T-cells and NK cells derived from iPSCs engineered with ADRs. As of February 15, 2024, the portfolio includes one issued patent and 14 pending applications broadly applicable to making and using ADR-expressing effector cells, including T-cells and NK cells differentiated from iPSCs engineered with ADRs. We expect U.S. patents related to this technology to have statutory expiration dates starting in 2039.

Intellectual Property Relating to CRISPR Engineering

In August 2019, we entered into a license agreement with Inscripta, Inc. Under the license agreement, we obtained a royalty-free, irrevocable license to a patent portfolio covering the composition, production and use of MAD7, a novel gene-editing CRISPR endonuclease from the *Eubacterium rectale* genome. The intellectual property includes issued patents and pending applications broadly applicable to MAD7 and the editing of mammalian cells. Our license covers the making and using of MAD7 for editing iPSCs, making master engineered iPSC lines and using master engineered iPSC lines to manufacture human therapeutic products. We expect U.S. patents related to this work to have statutory expiration dates starting in 2037.

Intellectual Property Relating to the Programming of Hematopoietic Cells

As of February 18, 2023 February 15, 2024, we own 18 16 families of U.S. and foreign patents and pending patent applications covering our cell programming technology and compositions of programmed cellular immunotherapies. This portfolio includes over 150 issued patents or pending patent applications relating to methods of programming the biological properties and therapeutic function of cells *ex vivo*, and the resulting therapeutic compositions of hematopoietic and immune cells. Patents and patent applications in this portfolio include claims covering (i) therapeutic compositions of hematopoietic and immune cells, including T cells, T-cells, NK cells, and $CD34^+$ cells, that

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have been programmed *ex vivo* with one or more agents to optimize their therapeutic function for application in oncology and immune disorders diseases and (ii) methods of programming cells including by the activation or inhibition of therapeutically-relevant genes and cell-surface proteins, such as those involved in the homing, proliferation and survival of hematopoietic cells or those involved in the persistence, proliferation and reactivity of immune cells. Any U.S. patents within this portfolio that have issued or may yet issue from pending patent applications will have statutory expiration dates between 2030 2033 and 2043 2044.

expiration dates between 2036 2032 and 2043. 2044.

Our Material Technology License Agreements

The University of Minnesota

In December 2016, we entered into a license agreement with the Regents of the University of Minnesota for rights relating to compositions and methods relating to NK cells, to modifications of cytotoxic receptors naturally expressed on NK cells including the CD16 Fc receptor, and to CARs for expression on NK cells. Under our agreement with the University of Minnesota, we acquired an

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exclusive royalty-bearing, sublicensable, worldwide license to make, use and sell licensed products in all fields for commercial purposes. The licensed patent rights are described in more detail above under “Intellectual Property Relating to the Programming of Hematopoietic Cells.” The University of Minnesota retains the right to practice the patent rights for research, teaching and educational purposes, including in corporate-sponsored research subject to certain limitations during the initial three years of the license agreement. The University of Minnesota also retains the right to license other academic and non-profit research institutes to practice the patent rights for research, teaching and educational purposes, but not for corporate-sponsored research. Our license is also subject to pre-existing rights of the U.S. government.

Under the terms of the license agreement, we are required to pay the University of Minnesota an annual license maintenance fee during the term of the agreement, and are also required to make payments of up to $4.6 million for development, regulatory and commercial milestones achieved with respect to each of the first three licensed products. If commercial sales of a licensed product commence, we will also be required to pay royalties at percentage rates in the low-single digits on net sales of licensed products. Our royalty payments are subject to reduction for any third-party payments required to be made until a minimum royalty percentage has been reached. In the event that we sublicense the patent rights, the University of Minnesota is also entitled to receive a percentage of the sublicensing income received by us.

Under the license agreement with the University of Minnesota, we are obligated to use commercially reasonable efforts to develop and make commercially available licensed products. In particular, we are required to conduct activities toward specific development milestones of licensed products on an annual basis.

The license agreement will continue until the abandonment of all patent rights or expiration of the last to expire licensed patent. The University of Minnesota may terminate the agreement if we default in the performance of any of our obligations and fail to cure the default within a specified grace period. The University of Minnesota may also terminate the agreement if we cease to carry out our business or become bankrupt or insolvent. We may terminate the agreement for any reason upon prior written notice to the University of Minnesota and payment of all amounts due to the University of Minnesota through the date of termination.

Memorial Sloan Kettering Sloan-Kettering Cancer Center (MSKCC)

In May 2018, we entered into an amended and restated license agreement with Memorial Sloan Kettering Cancer Center. MSKCC. The agreement amends and restates the exclusive license agreement we entered into with Memorial Sloan Kettering Cancer Center MSKCC in August 2016, under which we obtained rights relating to compositions and methods covering iPSC-derived cellular immunotherapy, including T cells T-cells and NK cells derived from iPSCs engineered with CARs. Pursuant to the amended and restated license agreement, we continue to hold exclusive rights to the foregoing patents and patent applications, and obtained additional licenses to certain patents and patent applications relating to compositions and methods covering novel CAR constructs as well as off-the-shelf CAR T cells, T-cells, including the use of CRISPR and other innovative technologies for their production.

Under our amended and restated agreement with Memorial Sloan Kettering Cancer Center, MSKCC, we have royalty-bearing worldwide licenses to make, use and sell licensed products in all fields for human therapeutic uses. The licensed patent rights are described in more detail above under “Intellectual Property Relating to iPSC Technology.” For those patent families where our rights are exclusive, Memorial Sloan Kettering Cancer Center MSKCC retains the right to practice the patent rights for research, teaching and non-clinical research purposes, and to license other academic and non-profit research institutes to practice the patent rights for research, teaching and non-clinical research purposes. Our licenses are also subject to pre-existing rights of the U.S. government.

Under the terms of the amended and restated agreement, we are required to pay Memorial Sloan Kettering Cancer Center MSKCC an annual license maintenance fee during the term of the agreement, and are also required to make payments of up to $12.5 million for development, regulatory and commercial milestones achieved with respect to each licensed products. If commercial sales of a licensed product commence, we will also be required to pay royalties at percentage rates up to the high-single digits on net sales of licensed products. Our royalty payments are subject to reduction for any third-party payments required to be made until a minimum royalty percentage has been reached. In the

event that we sublicense the patent rights, Memorial Sloan Kettering Cancer Center MSKCC is also entitled to receive a percentage of the sublicensing income received by us. Additionally, in the event a licensed product achieves a specified clinical milestone, Memorial Sloan Kettering Cancer Center MSKCC is then eligible to receive additional milestone payments, where the amount of such payments owed to Memorial Sloan Kettering Cancer Center MSKCC are contingent upon certain increases in the price of our common stock following the date of achievement of such clinical milestone.

Under the amended and restated agreement with Memorial Sloan Kettering Cancer Center, MSKCC, we are obligated to use commercially reasonable efforts to develop and make commercially available licensed products. In particular, we are required to conduct activities and commit a minimum amount of funding toward specific development milestones of licensed products on an annual basis.

The agreement will continue until the abandonment of all patent rights or expiration of the last to expire licensed patent. Memorial Sloan Kettering Cancer Center MSKCC may terminate the agreement if we default in the performance of any of our obligations and fail to cure the default within a specified grace period, if we cease to carry out our business or become bankrupt or insolvent, or if we

institute a proceeding to challenge the patent rights. We may terminate the agreement for any reason upon prior written notice to Memorial Sloan Kettering Cancer Center. MSKCC.

Max Delbruck Center

In December 2018, we entered into a license agreement with Max Delbruck Center for Molecular Medicine (MDC) for rights relating to novel humanized antibody fragments, antigen-binding domains and CAR constructs that uniquely target and specifically bind B-cell Maturation Antigen (BCMA). BCMA. Under our license agreement with MDC, we acquired an exclusive royalty-bearing, sublicensable, worldwide license to make, use and sell products covered by the licensed patent rights, and to perform licensed processes, in each case, using cells derived from allogeneic engineered stem cells. MDC retains a non-exclusive right to use the technology for its own internal research, teaching, and educational purposes.

Under the terms of the license agreement, we are required to pay to MDC an annual license maintenance fee during the term of the agreement. We also are required to make product development, regulatory and sales milestones payments to MDC of up to $11 million per product. If commercial sales of a licensed product commence, we will pay MDC royalties at percentage rates ranging in the low single digits on net sales of licensed products in countries where such product is protected by patent rights. Our obligation to pay royalties continues on a country-by-country basis until the expiration of all licensed patent rights covering licensed products in such country, and our royalty payments will be reduced by other payments we are required to make to third parties in certain circumstances until a minimum royalty percentage has been reached. In the event that we sublicense the patent rights, MDC is also entitled to receive a percentage of the sublicensing income received by us.

Under the license with MDC, we are obligated to use commercially reasonable efforts to develop and obtain approval of a licensed product.

The agreement will expire concurrently with patent rights on a country-by-country basis. We may terminate the agreement by providing prior written notice to MDC, and MDC has the right to terminate the agreement if we materially breach the agreement and fail to cure such breach within a specified grace period.

Whitehead Institute for Biomedical Research

In February 2009, we entered into a license agreement with the Whitehead Institute for Biomedical Research, as amended in October 2009 and September 2010, for rights relating to compositions and methods for reprogramming somatic cells to a less differentiated or pluripotent state. Under our agreement with the Whitehead Institute, we acquired an exclusive royalty-bearing, sublicensable, worldwide license to make, use and sell licensed products in all fields for commercial purposes, excluding the sale or distribution of reagents for basic research use. The licensed patent rights are described in more detail above under “Intellectual Property Relating to iPSC Technology.” The Whitehead Institute retains the right to practice the patent rights for research, teaching and educational purposes, including in corporate-sponsored research under limited circumstances and in some cases only after obtaining our consent. The Whitehead Institute also retains the right to license other academic and non-profit research institutes to practice the patent rights for research, teaching and educational purposes, but not for corporate-sponsored research. Our license is also subject to pre-existing rights of the U.S. government.

Under the terms of the license agreement, we are required to pay the Whitehead Institute an annual license maintenance fee during the term of the agreement, and are also required to make payments of up to $2.3 million for development and regulatory milestones achieved with respect to licensed products. If commercial sales of a licensed product commence, we will also be required to pay royalties at percentage rates in the low-single digits on net sales of licensed products. Our royalty payments are subject to reduction for any third-party payments required to be made until a minimum royalty percentage has been reached. In the event that we sublicense the patent rights, the Whitehead Institute is also entitled to receive a percentage of the sublicensing income received by us.

Under the license agreement with the Whitehead Institute, we are obligated to use commercially reasonable efforts to develop and commercialize licensed products, and to make licensed products or processes reasonably available to the public. In particular, we are required to commit a minimum amount of funding toward the development of a licensed product on an annual basis or conduct activities toward specific development milestones.

The agreement will continue until the abandonment of all patent rights or expiration of the last to expire licensed patent. The Whitehead Institute may terminate the agreement if we default in the performance of any of our obligations and fail to cure the default within a specified grace period, or if we institute a proceeding to challenge the patent rights. The Whitehead Institute may also terminate the agreement if we cease to carry out our business or become bankrupt or insolvent. We may terminate the agreement for any reason upon prior written notice to the Whitehead Institute and payment of all amounts due to the Whitehead Institute through the date of termination.

The Scripps Research Institute

We have entered into various license agreements with The Scripps Research Institute (TSRI) for rights relating to compositions and methods for reprogramming somatic cells, including the use of various small molecule classes and compounds in the reprogramming and maintenance of iPSCs. Under our agreements with TSRI (the TSRI License Agreements), we acquired exclusive royalty-bearing, sublicensable, worldwide licenses to make, use and sell products covered by the licensed patent rights, and to perform licensed processes, in each case, in all fields. The licensed patent rights are described in more detail above under “Intellectual Property Relating to iPSC Technology.” TSRI retains a non-exclusive right to practice and use the patent rights for non-commercial educational and research purposes, and to license other academic and non-profit research institutions to practice the patent rights for internal basic research and education purposes. Under certain of our TSRI License Agreements, other third parties maintain a right to practice the patent rights for their internal use only. Our license is also subject to pre-existing rights of the U.S. government.

Under the terms of the TSRI License Agreements, we are required to pay to TSRI annual minimum fees during the term of each agreement. Additionally, upon the achievement of specific regulatory and commercial milestones, we are required to make payments to TSRI of up to approximately $1.8 million under each of the TSRI License Agreements. We will also be required to pay TSRI royalties at percentage rates ranging in the low- to mid-single digits on net sales of licensed products. In the event that we sublicense the patent rights, TSRI is also entitled to receive a percentage of the sublicensing income received by us.

Under the TSRI License Agreements, we are obligated to use commercially reasonable efforts to meet the development benchmarks set out in development plans under each of the TSRI License Agreements, or otherwise expend a minimum specified amount per year for product development. TSRI has the right to terminate any TSRI License Agreement if we fail to perform our obligations under the applicable agreement, including failure to meet any development benchmark or to use commercially reasonable efforts and due diligence to develop a licensed product, or if we otherwise breach the agreement, challenge the licensed patent rights, are convicted of a felony involving the development or commercialization of a licensed product or process, or become insolvent. We may terminate any of our TSRI License Agreements by providing ninety days’ written notice to TSRI. Each TSRI License Agreement otherwise terminates upon the termination of royalty obligations under such agreement.

Dana-Farber Cancer Institute (DFCI)

In April 2020, we entered into a license agreement with the Dana-Farber Cancer Institute (DFCI) DFCI for rights relating to novel antibody fragments that uniquely and specifically bind the alpha-3 domain of MICA/B. Under our license agreement with DFCI, we acquired an exclusive royalty-bearing, sublicensable, worldwide license to make, use and sell products covered by the licensed patent rights in the field of iPSC-derived cellular therapeutics for the treatment of human disease, and a non-exclusive royalty-bearing, sublicensable, worldwide license to make, use and sell products covered by the licensed patent rights in the field of cellular therapeutics for the treatment of human disease. DFCI retains the right to practice and to license to other academic, government and non-profit institutes to practice the patent rights for research, teaching and education purposes, as well as to license third parties to practice the patents rights to make or sell research reagents or other research tools solely for use in research. Our licenses are

also subject to pre-existing rights of the U.S. government.

Under the terms of the license agreement, we are required to make minimum annual payments to DFCI throughout the term of the agreement. We also are required to make development, commercialization and sales milestones payments to DFCI of up to $25 million per licensed product. If commercial sales of a licensed product commence, we will pay DFCI royalties at percentage rates

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ranging in the low single digits on net sales of licensed products in countries where such product is protected by licensed patent rights. Our obligation to pay royalties continues on a country-by-country basis until the expiration of all licensed patent rights covering licensed products in such country, and our royalty payments will be reduced by other payments we are required to make to third parties in certain circumstances until a minimum royalty percentage has been reached. In the event that we sublicense the patent rights, DFCI is also entitled to receive a percentage of the sublicensing income received by us.

Under our agreement with DFCI, we are obligated to use reasonable efforts to develop and bring one or more licensed products to the marketplace through a program of development, production and distribution, including by meeting certain diligence benchmarks with respect to exclusively licensed products.

The agreement will continue until the expiration of the last to expire licensed patent. DFCI may terminate the agreement for cause, including if we default in the performance of any of our obligations and fail to cure the default within a specified grace period, if an officer of ours (or of an affiliate or sublicensee) is convicted of a felony related to the manufacture, use, sale or important or a licensed product, if we cease to carry out our business or become bankrupt or insolvent, and if we institute a proceeding to challenge the patent rights. DFCI may also terminate our exclusive license if we fail to materially comply with our diligence obligations. We may terminate the agreement for any reason in its entirety or on a product-by-product or country-by-country basis upon prior written notice to DFCI and payment of all amounts due to DFCI through the date of termination.

Table Baylor College of Contents Medicine (BCM)

In April 2020, we entered into a license agreement with BCM for rights pertaining to a novel ADR that selectively targets activated T-cells to protect engineered allogeneic effector cells expressing the ADR from elimination in the host immune system. Under our agreement, we obtained an exclusive royalty-bearing, sublicensable, worldwide license to make, use and sell products covered by the licensed patent rights in the field of iPSC-derived cell products, including T-cells and NK cells derived from iPSCs engineered with ADRs. BCM retains the right to practice and license to other academic, government and research institutes for non-commercial research purposes. Our licenses are also subject to pre-existing rights of the U.S. government.

Under the terms of the license agreement, we are obligated to make a minimum annual royalty payment to BCM starting in 2024. We are also required to make development and regulatory milestone payments to BCM for the first three (3) distinct licensed products, where the milestone payments total up to $7 million for the first licensed product, and are reduced by fifty percent (50%) for each of the second and third licensed products. If commercial sales of a licensed product commence, we will pay BCM a low single-digit percentage royalty on net sales of licensed products in countries where the product is protected by licensed patent rights. Our obligation to pay royalties continues on a country-by-country basis until the expiration of all licensed patent rights in that country, with possible reductions for payments that we are required to make to third parties. In the event that we sublicense the patent rights, BCM is entitled to receive a percentage of our sublicensing income.

Under the license agreement, we are obligated to use reasonable efforts to develop and introduce licensed products to the commercial market including by meeting certain diligence timelines. These timelines are extendable by us for one year upon a one-time payment, subject to BCM's discretion for further extensions.

The license agreement remains in effect until the expiration of the last to expire licensed patent. BCM has the right to terminate the agreement if we materially default in the performance of any terms and fail to correct the default within a specified grace period after BCM's written notice. Termination by BCM is also possible if we are subject to insolvency or similar proceedings, assignment of all or substantially all of our assets for the benefit of creditors, or the appointment of a trustee, in each case that are not dismissed, stayed or suspended within thirty (30) days following such events. We retain the right to terminate the agreement for any cause, upon prior written notice to BCM and payment of all amounts due to BCM under the agreement.

Manufacturing

Off-the-shelf, Multiplexed-engineered, iPSC-derived Cellular Immunotherapies

The manufacture of our off-the-shelf, multiplexed-engineered, iPSC-derived cellular immunotherapy CAR NK cell and CAR T-cell product candidates involves a three-stage process:

- The first stage is intended to generate a clonal master iPSC line and generally consists of the following steps: (i) obtain appropriately-consented healthy human donor cells, such as fibroblasts or hematopoietic cells, and conduct transfusion transmissible disease testing on the donor cells; (ii) induction of pluripotency in the donor cells using a proprietary transgene integration-free and footprint-free method of reprogramming; (iii) genetic engineering of iPSCs; and (iv) isolation and selection of a single iPSC, followed by clonal expansion of the single iPSC to produce a clonal master iPSC line for cell product manufacture.

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- The second stage is intended to derive the cell product population of interest and generally consists of the following steps: (i) expansion and differentiation of the clonal master iPSC line to produce $CD34^+$ definitive hematopoietic progenitor cells; and (ii) further expansion and differentiation of these progenitor cells to produce the cell product population of interest.
- The third stage is intended to derive the final cell product and generally consists of the following steps: (i) washing the cell product population; (ii) formulating the cell product population in an infusion media for intravenous administration of the final cell product; and (iii) cryopreserving individual aliquots of the final cell product and storing these aliquots in single-dose infusion bags.

As part of our manufacturing process, we endeavor to utilize current Good Manufacturing Process (cGMP) grade materials and reagents, if commercially available; however, certain critical materials and reagents are currently qualified for research use only. Additionally, we obtain key components required for the manufacture of our iPSC-derived cell product candidates from third-party manufacturers and suppliers, which include, in some instances, sole source manufacturers and suppliers. We do not currently have long-term commitments or supply agreements in place to obtain certain key components used in the manufacture of our iPSC-derived cell product candidates.

We currently manufacture our iPSC-derived cell product candidates for use in research, preclinical development, and clinical development. We operate two cGMP-compliant manufacturing facilities for the clinical production of our iPSC-derived cell product candidates. Both of our manufacturing facilities are located in San Diego, California, and are custom designed for the production of off-the-shelf cell product candidates using clonal master iPSC lines as the starting cell source. Each of these state-of-the-art facilities have been commissioned and qualified, and we have been issued drug manufacturing licenses for each facility by the State of California, Department of Health Services, Food and Drug Branch. With the extension of manufacturing to our new corporate headquarters in 2022, we are positioned to support manufacturing and production of our product candidates for all phases of clinical development as well as initial commercialization.

We also contract with third parties, including medical center cell therapy facilities and contract manufacturing organizations (CMOs), for the conduct of some of the activities required to manufacture our iPSC-derived cell product candidates for use in clinical investigation. We expect that we will continue to contract with third parties, including medical center cell therapy facilities and CMOs, for the conduct of certain of the activities required to manufacture our iPSC-derived cell product candidates.

Marketing, Market Access & and Sales

We currently intend to commercialize any products that we may successfully develop. We currently have no experience in marketing, market access or selling therapeutic products. We may need to further evaluate and generate evidence beyond what is generated in our clinical programs that would satisfy the needs of payers and healthcare technology assessment (HTA) bodies. To market any of our products independently would also require us to develop a sales force with technical expertise along with establishing commercial infrastructure and capabilities. Our commercial strategy for marketing our product candidates also may include the use of strategic partners, distributors, a contract sales force or the establishment of our own commercial infrastructure. We plan to further evaluate these alternatives as we approach approval for the first of our product candidates.

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Government Regulation

In the United States, the FDA regulates biological products under the Federal Food, Drug, and Cosmetic Act (the FDCA) and the Public Health Service Act (the PHS Act) and related regulations. Biological products are also subject to other federal, state, local, and foreign statutes and regulations. The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of biological products. These agencies and other federal, state, local, and foreign entities regulate

the clinical development, manufacture and marketing of biological products. These agencies and other federal, state, local, and foreign entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, packaging, labeling, storage, distribution, record keeping, reporting, approval or licensing, advertising and promotion, and import and export of our products. Failure to comply with the applicable U.S. regulatory requirements at any time during the product development process or after approval may subject an applicant to administrative or judicial sanctions. FDA sanctions include refusal to approve pending applications, withdrawal of an approval or suspension or revocation of a license, clinical hold, warning or untitled letters, voluntary or mandatory product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties. In addition, government regulation may delay or prevent marketing of product candidates for a considerable period of time and impose costly procedures upon our activities.

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Marketing Approval

The process required by the FDA before biological products may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory and animal tests according to good laboratory practices (GLPs) and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an IND application which must become effective before human clinical trials may begin;
- approval of the protocol and related documentation by an independent institutional review board or IRB, (IRB), or ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices (GCPs) and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use or uses;
- submission to the FDA of a Biologics License Application (BLA) for marketing approval that includes substantive evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA pre-approval inspection of manufacturing facilities where the product is produced to assess compliance with the FDA's cGMPs to assure that the facilities, methods and controls are adequate, and, if applicable, current good tissue practices (cGTPs) for the use of human cellular and tissue products to prevent the introduction, transmission or spread of communicable diseases;
- potential FDA audit of the nonclinical study sites and clinical trial sites that generated the data in support of the BLA;
- review of the product candidate by an FDA advisory committee where appropriate, if applicable;
- payment of user fees for FDA review of the BLA (unless fee waiver applies); and
- FDA review and approval, or licensure, of the BLA which must occur before a biological product can be marketed or sold.

U.S. Biological Products and Drug Development Process

Before testing any biological product candidate in humans, nonclinical tests, including laboratory evaluations and animal studies to assess the potential safety and activity of the product candidate, are conducted. The conduct of the nonclinical tests must comply with federal regulations and requirements including GLPs.

Prior to commencing the first clinical trial, the trial sponsor must submit the results of the nonclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of an initial IND application. Some nonclinical testing may continue even after the IND application is submitted. The IND application automatically becomes effective 30 days after receipt by the FDA unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial and places the trial on a clinical hold. In such case, the sponsor of the IND application must resolve any outstanding concerns with the FDA before the clinical trial may begin. The FDA also may impose a clinical hold on ongoing clinical trials due to safety concerns or non-compliance. If a clinical hold is imposed, a trial may not recommence without

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FDA authorization and then only under terms authorized by the FDA. A clinical hold may either be a full clinical hold or a partial clinical hold that would limit a trial, for example, to certain doses or for a certain length of time or to a certain number of subjects. Further, an independent IRB for each site

limit a trial, for example, to certain doses or for a certain length of time or to a certain number of subjects. Further, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that site. An IRB is charged with protecting the welfare and rights of study subjects and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee. This group provides authorization as to whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the trial and may recommend halting the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

Clinical trials involve the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. 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 to be used to monitor subject safety, including rules that assure a clinical trial will be stopped if certain adverse events occur. Each protocol and any amendments to the protocol must be submitted to the FDA and to the IRB. Information about

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certain clinical studies must be submitted with specific timeframes to the National Institutes of Health for public dissemination at www.clinicaltrials.gov.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap:

- Phase 1—The investigational product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients. These trials may also provide early evidence on effectiveness.
- Phase 2—These trials are conducted in a limited number of patients in the target population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3—Phase 3 trials are undertaken to provide statistically significant evidence of clinical efficacy and to further evaluate dosage, potency, and safety in an expanded patient population at multiple clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the product has been obtained, and are intended to establish the overall benefit-risk relationship of the investigational product, and to provide an adequate basis for product approval and physician labeling.
- Phase 4 – 4—In some cases, the FDA may condition approval of a BLA for a product candidate on the sponsor's agreement to conduct additional clinical studies to further assess the candidate's safety and effectiveness after approval. Such post-approval trials are typically referred to as Phase 4 clinical trials. The FDA has statutory authority to require post-market clinical trials to address safety issues. A sponsor may also voluntarily conduct additional clinical studies after approval to gain more information about their product. All of these trials must be conducted in accordance with GCP requirements in order for the data to be considered reliable for regulatory purposes.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Within 15 calendar days after the sponsor determines that the information qualifies for reporting, written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events; any findings from other studies, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human subjects; or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information.

Regulatory authorities, a data safety monitoring board or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the participants are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the trial is not being conducted in accordance with the IRB's requirements or if the investigated product has been associated with unexpected serious harm to patients, and the trial may not recommence without the IRB's authorization.

Typically, if a product is intended to treat a chronic disease, safety and efficacy data must be gathered over an extended period of time, which can range from six months to three years or more.

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Concurrently with clinical trials, companies usually complete additional animal studies and must also develop additional information about the physical characteristics of the investigational product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with the use of biological products, the PHS Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency, and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

A drug being studied in clinical trials may be made available to individual patients in certain circumstances. Pursuant to the 21st Century Cures Act (the Cures Act), as amended, the manufacturer of an investigational drug for a serious disease or condition is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational drug. This requirement applies on the earlier of the first initiation of a Phase 2 or Phase 3 trial of the investigational drug, or as applicable, 15 days after the drug receives a designation as a breakthrough therapy, fast track product, or RMAT. Further, the Right to Try Act of 2017 among other things, provides a federal framework for certain patients to request access to certain investigational new drug IND products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try

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Act. We review each individual request for access through the Cures Act, the Right to Try Act and similar state laws, and may or may not provide access depending upon the facts of each request.

U.S. Review and Approval Processes

In order to obtain approval to market a biological product in the United States, a BLA must be submitted to the FDA that provides data establishing to the FDA's satisfaction the safety, purity and potency of the investigational product for the proposed indication. A BLA includes all data available from nonclinical studies and clinical trials, together with detailed information relating to the product's manufacture and composition, and proposed labeling.

Under the Prescription Drug User Fee Act (PDUFA), as amended, each BLA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's fee schedule, effective through September 30, 2023, the user fee for an application requiring clinical data, such as a BLA and an NDA, is $3,242,026. PDUFA also imposes an annual prescription drug product program fee for biologics and drugs ($393,933). drugs. 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 having fewer than 500 employees. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. After the BLA submission is accepted for filing, the FDA reviews the BLA to determine, among other things, whether the proposed product is safe and effective for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMPs to assure and preserve the product's identity, safety, strength, quality, potency, and purity, and for a biological product, whether it meets the biological product standards. The FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee, typically comprised of clinicians and other experts, for evaluation and a recommendation as to whether the application should be approved and, if so, 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 a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. For a human cellular or tissue product, the FDA also will not approve the product if the manufacturer is not in compliance with cGTPs. FDA regulations also require tissue establishments to register and list their human cells, tissues, and cellular and tissue based products (HCT/Ps) with the FDA and, when applicable, to evaluate donors through screening and testing. Additionally, before approving a BLA, the FDA may inspect clinical sites to assure that the clinical trials were conducted in compliance with IND study requirements and GCPs. If the FDA determines

the manufacturing process or manufacturing facilities are not acceptable, it typically will outline the deficiencies and often will require the facility to take corrective action and provide documentation evidencing the implementation of such corrective action, which may delay further review of the application. If the FDA finds that a clinical site did not conduct the clinical trial in accordance with GCPs, the FDA may determine the data generated by the site should be excluded from the primary efficacy analyses provided in the BLA, and request additional testing or data. Additionally, the FDA ultimately may still decide that the application does not satisfy the regulatory criteria for approval.

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The FDA also has authority to require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers to ensure that the benefits of a biological product outweigh its risks. A sponsor may also voluntarily propose a REMS as part of the BLA submission. The need for a REMS is determined as part of the review of the BLA. Based on statutory standards, elements of a REMS may include "dear doctor letters," a medication guide, more elaborate targeted educational programs, and in some cases restrictions on distribution. These elements are negotiated as part of the BLA approval, and in some cases may delay the approval date. Once adopted, REMS are subject to periodic assessment and modification.

After the FDA completes its initial review of a BLA, it will communicate to the sponsor that the biological product will either be approved, or it will issue a complete response letter to communicate that the BLA will not be approved in its current form. The complete response letter usually describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA to address all of the deficiencies identified in the letter, or withdraw the application, or request a hearing.

One of the performance goals of the FDA under PDUFA is to review 90% of standard BLAs in 10 months and 90% of priority BLAs in six months, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs and its review goals are subject to change from time to time. The review process and the PDUFA goal data may be extended by three months if the FDA requests or the BLA applicant otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

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Even if a product candidate receives regulatory approval, the approval may be limited to specific disease states, patient populations and dosages, or the indications for use may otherwise be limited. Further, the FDA may require that certain contraindications, warnings, or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require Phase 4 post-marketing clinical trials and testing and surveillance programs to monitor the safety of approved products that have been commercialized. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in the imposition of new restrictions on the product or complete withdrawal of the product from the market.

Post-Approval Requirements

Products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, requirements relating to monitoring, record-keeping, advertising and promotion, reporting of adverse experiences, and limitations on industry-sponsored scientific and educational activities. Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or a BLA supplement, which may require the development of additional data or preclinical studies and clinical trials.

FDA regulations require that approved products be manufactured in specific approved facilities and in accordance with cGMP regulations which require, among other things, quality control and quality assurance, the maintenance of records and documentation, and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics, and those supplying products, ingredients, and components of them, are required to register their establishments with the FDA and certain state agencies, and are subject to periodic announced and unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other regulatory requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA does not regulate behavior of physicians in their choice of treatments and physicians may legally prescribe available products for uses that are not described in the product's labeling and that differ from those approved by the FDA. However, the FDA does restrict an applicant's communications on the subject of off-label use of their products. The FDA and other agencies actively enforce the laws prohibiting the marketing and promotion of off-label uses, and a company that is found to have improperly marketed or promoted off-label use may be subject to significant liability, including criminal and civil penalties under the FDCA and False Claims Act, exclusion from participation in federal healthcare programs, and mandatory compliance programs.

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The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, restrictions on a product, and judicial or administrative enforcement.

Expedited Development and Review Programs

The FDA is authorized to designate certain products for expedited review if they demonstrate the potential to address an unmet medical need in the treatment of a serious or life-threatening disease or condition for which there is no effective treatment. These programs are referred to as fast track designation, priority review, accelerated approval, breakthrough therapy designation, and regenerative advanced therapy designation.

Fast Track Designation. The FDA may grant "fast track" status to product candidates that are intended to treat serious or life-threatening diseases or conditions and demonstrate the potential to address an unmet medical need for the condition. Fast track is a process designed to facilitate the development and expedite the review of such product candidates by providing, among other things, more frequent meetings with the FDA to discuss the product candidate's development plan and rolling review, which allows submission of individually completed sections of an BLA for FDA review before the entire submission is completed. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a product candidate may request the FDA to designate the product as a fast track product at any time during clinical development. Fast track status does not ensure that a product will be developed more quickly or receive FDA approval. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process, or if the designated drug development program is no longer being pursued.

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Priority Review. The FDA may give a priority review designation to a product candidate if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or to provide a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. Priority review is intended to reduce the time it takes for the FDA to review a BLA, with the goal to take action on the application within six months from when the application is filed, compared to ten months for a standard review. The FDA will attempt to direct additional resources to the evaluation of an application for a biological product or drug designated for priority review in an effort to facilitate the review.

Accelerated Approval. Additionally, a product may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that 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 a condition of approval, the FDA may require that a sponsor of a biological product or drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials with due diligence and, under the Food and Drug Omnibus Reform Act of 2022 (FDORA), the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. In addition, the FDA currently requires, unless otherwise informed by the agency, pre-approval of promotional materials for products being considered for accelerated approval. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

Breakthrough Therapy Designation. A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible

for breakthrough therapy designation if preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. If so designated, the FDA will expedite the development and review of the product candidate's marketing application, including by meeting with, and providing advice to, the sponsor throughout the product candidate's development, and taking steps to facilitate an efficient review of the development program and to ensure that the design of the clinical trials is as efficient as practicable.

RMAT Designation. As part of the Cures Act, Congress amended the FDCA to create an accelerated approval program for regenerative advanced therapies. To qualify for this program, and be granted regenerative advanced medicine therapy (RMAT) designation, a product must be a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or a combination of such products, and not a product solely regulated as a human cell and tissue product. This program is intended to facilitate efficient development and expedite review of regenerative advanced therapies, which are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and preliminary clinical evidence must indicate that the product candidate has the potential to address an unmet need for such disease or condition. A BLA for a product candidate that has received RMAT designation may be eligible for priority review or accelerated approval through (1) surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit or (2) reliance upon data obtained from a meaningful number of sites. Benefits of such designation also include

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early interactions with FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A designated RMAT product candidate that is granted accelerated approval and is subject to post approval requirements may fulfill such requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post approval monitoring of all patients treated with such therapy prior to its approval.

Designated Platform Technology Status. Under FDORA, a platform technology incorporated within or utilized by a drug or biological product is eligible for designation as a designated platform technology if (1) the platform technology is incorporated in, or utilized by, a drug approved under a BLA or NDA; (2) preliminary evidence submitted by the sponsor of the approved or licensed drug, or a sponsor that has been granted a right of reference to data submitted in the application for such drug, demonstrates that the platform technology has the potential to be incorporated in, or utilized by, more than one drug without an adverse effect on quality, manufacturing, or safety; and (3) data or information submitted by the applicable person indicates that incorporation or utilization of the platform technology has a reasonable likelihood to bring significant efficiencies to the drug development or manufacturing process and to the review process. A sponsor may request the FDA to designate a platform technology as a designated platform technology concurrently with, or at any time after, submission of an IND application for a drug that incorporates or utilizes the platform technology that is the subject of the request. If so designated, the FDA may expedite the development and review of any subsequent original BLA for a drug that uses or incorporates the platform technology. Designated platform technology status does not ensure that a drug will be developed more quickly or receive FDA approval. In addition, the FDA may revoke a designation if the FDA determines that a designated platform technology no longer meets the criteria for such designation.

RTOR. The FDA may review applications for oncology products under Real-Time Oncology Review (RTOR) established by the FDA's Oncology Center of Excellence. RTOR, which allows an applicant to pre-submit components of the application to allow the FDA to review clinical data before the complete filing is submitted, aims to explore a more efficient review process to ensure that safe

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and effective treatments are available to patients as early as possible, while maintaining and improving review quality. Products considered for review under RTOR must, among other things, be likely to demonstrate substantial improvements on a clinically relevant endpoint(s) over available therapy, and must have easily interpreted endpoints. In addition, no aspect of the application should be likely to require a longer review time, such as, for example, a requirement for a REMS. To determine eligibility for RTOR, the FDA requires top-line efficacy and safety results from an applicant's pivotal clinical trial(s), as well as completion of database lock for the clinical trial(s). The FDA will generally make a decision regarding acceptance into RTOR within twenty (20) business days of receipt of the request from the applicant. If an applicant is not accepted into RTOR, the applicant will follow routine application submission procedures.

Fast Track designation, priority review, accelerated approval, breakthrough therapy designation, RMAT designation, and designated platform technology status, and RTOR do not change the standards for approval but may expedite the development or approval process. Moreover, even if a product candidate or platform technology qualifies for one or more of these programs, the FDA may later decide that the product candidate or platform technology no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

U.S. Patent Term Restoration and Marketing Exclusivity

Under certain circumstances, U.S. 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. Patent term restoration can compensate for time lost during product development and the regulatory review process by returning up to five years of patent life for a patent that covers a new product or its use. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The period of patent term restoration is generally one-half the time between the effective date of an IND application (falling after issuance of the patent) and the submission date of a BLA, plus the time between the submission date of the BLA and the approval of that application, provided the sponsor acted with diligence. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The application for patent term extension is subject to approval by the U.S. Patent and Trademark Office in consultation with the FDA. A patent term extension is only available when the FDA approves a biological product or drug for the first time.

With the Hatch-Waxman Amendments, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the FDCA. To obtain approval of a generic drug, an applicant must submit to the agency an abbreviated new drug application (ANDA) which relies on the preclinical and clinical testing previously conducted for a drug approved under an NDA, known as the reference listed drug (RLD). For the ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. The FDA must also determine that the generic drug is bioequivalent to the innovator drug.

An abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009, which was part of the Patient Protection and Affordable Care Act of 2010 (ACA). This amendment to the PHS Act attempts to minimize duplicative testing. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a biological product is biosimilar to the reference biological product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the product and the reference product may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product.

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A reference biological product is granted twelve years of exclusivity from the time of first licensure of the reference product. The first biological product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitting under the abbreviated approval pathway for the lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant's favor of a lawsuit challenging the biologic's patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period.

A biological product or drug can obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods for all formulations, dosage forms, and indications of the active moiety or the biological period and, for drugs, patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or, for drugs, patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study. study provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan drug designation to biological products and drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a biological product or drug in the United States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the applicant, the name of the therapeutic agent and its designated 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.

If a biological product or drug that receives orphan drug designation is the first such product approved by FDA for the orphan indication, it receives orphan product exclusivity, which for seven years prohibits the FDA from approving another application to market the same product for the

same indication. Orphan product exclusivity will not bar approval of another product under certain circumstances, including if the new product is shown to be clinically superior to the approved product on the basis of greater efficacy or safety or a demonstration that the new product otherwise makes a major contribution to patient care. More than one product may also be approved by the FDA for the same orphan indication or disease as long as the products are different. If a biological product or drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity. Orphan drug status in the European Union has similar, but not identical, benefits.

Pediatric Research Equity Act

Under the Pediatric Research Equity Act (PREA), as amended, a BLA or supplement must contain data to assess the safety and effectiveness of the biological product or drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The intent of the PREA is to compel sponsors whose products have pediatric applicability to study those products in pediatric populations. The FDCA requires manufacturers of biological products and drugs that include a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration to submit a pediatric study plan to the FDA as part of the IND application. The plan must be submitted not later than 60 days after the end-of-Phase 2 meeting with the FDA; or if there is no such meeting, before the initiation of any Phase 3 trials or a combined Phase 2 and Phase 3 trial; or if no such trial will be conducted, no later than 210 days before submitting a marketing application or supplement. The FDA may grant deferrals for submission of data or full or partial waivers. Generally, the PREA does not apply to any biological product or drug for an indication for which orphan designation has been granted.

Coverage and Reimbursement

Sales of our products, when and if approved, will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. In the United States, no uniform policy of coverage and reimbursement for drug or biological products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis. Additionally, coverage determinations often require generating additional evidence related, for example, to the relative costs and benefits of new therapies versus standard of care – which goes beyond the data able to be generated within our clinical programs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of their cost.

In the United States, for example, principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services or CMS, (CMS), which decides whether and to what extent a new product will be covered and reimbursed under Medicare. Private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial

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degree. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. As a result, coverage determination is often a

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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 obtained. Further, coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price-controls, restrictions on reimbursement and requirements for substitution of biosimilars for branded prescription drugs. 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 may be sold at lower prices than in the United States. In addition, many pharmaceutical manufacturers 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. Increasingly, third-party payors are also requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we

challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement.

In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its 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 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. 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 price structures of the United States and generally prices tend to be significantly lower.

Healthcare Reform and Other Regulatory Changes

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare.

For example, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, each as amended, collectively known as the ACA was enacted in the United States. The ACA includes measures that have significantly changed, and are expected to continue to significantly change, the way healthcare is financed by both governmental and private insurers. The ACA contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and changes to fraud and abuse laws. Among the provisions of the ACA of greatest importance to the pharmaceutical industry are that the ACA:

- subjects biological products to potential competition by biosimilars;
- made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability; and
- extended a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted include the following:

- The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. Subsequent legislation extended the 2% reduction which remains in effect through 2031. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation.
- On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which further reduced Medicare payments to several types of providers. providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.
- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.

- TableOn March 11, 2021, President Biden signed the American Rescue Plan Act of Contents

  2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024.

- The Inflation Reduction Act (the IRA) of 2022 (IRA) includes several provisions that may impact our business to varying degrees, including provisions that create a $2,000 reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D pricing price caps for certain high-cost drugs and biologics without generic or biosimilar competition, competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation, inflation; and delay until January 1, 2032 the implementation of the HHS rebate rule that would require pass through of have limited the fees that pharmacy

benefit manager rebates to beneficiaries. managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one rare disease orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple rare disease orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The effect implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

The costs of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. To date, there have been several recent U.S. congressional inquiries, as well as proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

At the state level, legislatures have increasingly passed legislation and implemented 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, designed to encourage importation from other countries and bulk purchasing. 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. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

Other Healthcare Laws and Compliance Requirements

Pharmaceutical 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. Arrangements with third-party payors and customers can expose pharmaceutical manufactures to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act or the FCA, (FCA) which may constrain the business or financial arrangements and relationships through which companies research, sell, market and distribute pharmaceutical products. In addition, transparency laws and patient privacy laws can apply to the activities of pharmaceutical manufactures. The applicable federal, state and foreign healthcare laws and regulations that can affect a pharmaceutical company's operations include without limitation:

- The federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under the Medicare and Medicaid programs, or other federal healthcare programs. A person or entity can be found guilty of

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violating the statute without actual knowledge of the statute or specific intent to violate it. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA or federal civil monetary penalties. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but such exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection;

- The federal civil and criminal false claims laws, including the FCA, and civil monetary penalty laws, which prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government or knowingly making, using or causing to be made or used a false record or statement, including providing inaccurate billing or coding information to customers or promoting a product off-label, material to a false or fraudulent claim to the federal government. As a result of a

modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the federal government. In addition, 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 FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created federal criminal statutes that prohibit, among other things, knowingly and willfully 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 the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their respective implementing regulations, which impose, among other things, specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates as well as their covered subcontractors. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions;
- The federal legislation commonly referred to as the Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to CMS, information related to payments or other transfers of value made to physicians, other licensed care professionals and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- Federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;
- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- Analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require the reporting of information related to drug pricing; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of

health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations with respect to certain laws. 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. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect our business in an adverse way. Changes in regulations, statutes 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; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. Ensuring our business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company’s attention from the business.

The failure to comply with any of these laws or regulatory requirements subjects companies to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in significant penalties,

including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical company to incur significant legal expenses and divert management's attention from the operation of the business.

Regulations Governing Data Collection and the Use, Processing and Cross-Border Transfer of Personal Information

We also may be or may become subject to various state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

For example, California has enacted the California Consumer Privacy Act (CCPA), which created new individual privacy rights for California consumers (as defined in the law) and placed increased requires compliance with privacy and security obligations on for entities handling personal data of consumers or households. Effective as of January 2020, the The CCPA requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt out of certain sales or transfers of personal information, and also regulates employee information. On November 3, 2020, California passed the The California Privacy Rights Act (CPRA) which builds on amended the CCPA and expands consumer privacy rights. rights in California, including by expanding consumers' rights with respect to certain sensitive personal information and by establishing a state agency vested with the authority to enforce the CCPA. The CPRA went into effect on January 1, 2023 and also applies to personal information collected on or after January 1, 2022. about employees, applicants and retirees, as well as that which is collected in a business-to-business capacity. While there is currently an exception in the CCPA and CPRA for protected health information that is subject to HIPAA, the CCPA and CPRA may nevertheless impact our business activities. Virginia and Colorado have also passed comprehensive privacy laws that became effective in 2023 and Several other U.S. states also are considering omnibus privacy have passed or enacted legislation similar to the CCPA, but contain key differences in the scope, application, and industry organizations regularly adopt and advocate for new standards in these areas. enforcement which may complicate compliance efforts.

In addition as of May 25, 2018, the EU General Data Protection Regulation (GDPR) (EU GDPR), as well as other national data protection legislation in force in relevant European Economic Area (EEA) Member States, and the UK equivalent of the same (UK GDPR) (collectively referred to as the GDPR in this Annual Report), and UK Data Protection Act 2018 regulates the collection and use processing of personal data in the European Union (EU) EEA and the United Kingdom (UK). The GDPR covers any business, regardless of its location, that provides goods or services to residents individuals in the EU EU/UK or monitors their behavior in the EEA/UK, and, thus, could incorporate any activities we undertake in EU member states. EEA/UK. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for "sensitive information," which includes health and genetic information, obtaining consent of the individuals residing in to whom the EU. The GDPR grants personal data relates, having legal bases for processing personal data, providing transparency information to individuals, implementing safeguards to protect the opportunity to object to the processing of their personal information, allows them to request deletion of personal information in certain circumstances, security and provides the individual with an express right to seek legal remedies in the event the individual believes his or her rights have been violated. Further, the GDPR imposes strict rules on the transfer confidentiality of personal data, out of having data processing agreements with third parties who process personal data, responding to individuals' requests to exercise their data protection rights, reporting personal data breaches to the EU to regions that have not been deemed to offer "adequate" privacy protections, such as the U.S. currently. competent national data protection authority and affected individuals, appointing data protection officers, ensuring certain accountability measures are in place and record keeping. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU member states, EEA Member States and the UK, which may deviate slightly from the GDPR, may result in warning letters, mandatory audits and financial penalties, including fines of up to 4% of global revenues, or €20,000,000, (£17.5 million for the UK GDPR), whichever is greater.

Further The GDPR also confers a private right of action on data subjects and consumer associations to the United Kingdom's (UK) exit lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from the EU on January 31, 2020, the GDPR ceased to apply in the UK at the end violations of the transition period on December 31, 2020. However, as GDPR.

The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime which is independent from but currently still aligned to the EU's data protection regime. Non-compliance However, the UK has announced plans to reform the country's data protection legal

framework in its Data Reform Bill, which will introduce significant changes from the EU GDPR. This may lead to additional compliance costs and could increase our overall risk exposure as we may no longer be able to take a unified approach across the EEA and the UK, and we will need to amend our processes and procedures to align with the new framework.

The GDPR also impose restrictions in relation to the international transfer of personal data from the EEA and UK GDPR may result to other countries in monetary penalties respect of up which the European Commission or the UK government has not issued a so-called "adequacy decision" or " adequacy regulation", including the US in certain circumstances, unless the parties to £17.5 million the transfer have implemented specific safeguards to protect the transferred personal data, such as the European Commission's Standard Contractual Clauses for transfers outside of the EEA (SCCs) and a similar transfer mechanism for transfers of personal data outside of the UK, the International Data Transfer Agreement or 4% Addendum (IDTA). Where relying on the SCCs or IDTA for data transfers, exporters are also required to carry out transfer impact assessments to assess the risk of worldwide revenue, whichever is higher. the data transfer on a case-by-case basis, including an analysis of the laws in the destination country. Although the UK is regarded as a third country under the EU's GDPR, the European Commission (EC) has now issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU EEA to the UK remain unrestricted. Like

In July 2023, the European Commission adopted its adequacy decision for the EU-U.S. Data Privacy Framework (Framework), the successor of the EU-U.S. Privacy Shield framework, which the Court of Justice of the European Union invalidated in 2020. On the basis of the new adequacy decision, personal data can flow safely from the EU to U.S. companies participating in the Framework, without having to put in place additional data protection safeguards. However, the Framework's validity has already been challenged in court.

Implementing mechanisms to endeavor to ensure compliance with the GDPR and relevant local legislation in EEA Member States and the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK may be onerous and may interrupt or delay our development activities, and adversely affect our business, financial condition, results of operations, and prospects. In addition to the EEA remain free flowing.foregoing, a breach of the CCPA, GDPR or other applicable privacy and data protection laws and regulations could result in regulatory investigations, reputational damage, and orders to cease/change our use of data, enforcement notices, or potential civil claims including class action-type litigation.

Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

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Competition

The biotechnology and pharmaceutical industries are characterized by rapid innovation, intense and dynamic competition and a strong emphasis on proprietary products. While we believe that our technology, proprietary iPSC product platform, scientific knowledge and experience in the field of cellular immunotherapy provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions, as well as standard-of-care treatments, new products undergoing development and combinations of existing and new therapies. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies, including antibody-based therapies such as bi-specific antibodies, and combinations thereof, that may become available in the future.

Cellular immunotherapies for the treatment of cancer and autoimmune diseases have recently been an area of significant research and development by academic institutions and biopharmaceutical companies. Novartis AG (Novartis) and Kite Pharma, Inc. (Kite) were the first to obtain FDA approval for Six autologous CAR T-cell therapies for have been approved by the treatment of certain cancers. Novartis obtained FDA approval to commercialize Kymriah in August 2017 for the treatment of children and young adults with relapsed / refractory B-cell acute lymphoblastic leukemia, in May 2018, for the treatment of adults with relapsed / refractory diffuse large B-cell lymphoma, and in May 2022 for the treatment of adult patients with relapsed / refractory follicular lymphoma. In October 2017, Kite obtained FDA approval to commercialize Yescarta for the treatment of adults with relapsed / refractory diffuse large B-cell lymphoma. Bristol-Myers Squibb received FDA approval in 2021 for two new, autologous T-cell therapy products – Breyanzi for the treatment of relapsed or / refractory hematologic malignancies: Kymriah (Novartis AG) for B-cell acute lymphoblastic leukemia (ALL) and for diffuse large B-cell lymphoma after two (DLBCL); Yescarta (Kite Pharma) for aggressive large B-cell lymphoma (LBCL); Tecartus (Kite Pharma) for mantle cell lymphoma or more lines of systemic therapy, B-cell ALL; Breyanzi (Bristol-Myers Squibb Company) for aggressive LBCL; Abecma (Bristol-Myers Squibb Company) for multiple myeloma; and Abecma Carvykti (Janssen Biotech) for the treatment of adult patients with relapsed or refractory multiple myeloma. More recently, Janssen Biotech, Inc. received FDA approval in February 2022 for Carvykti for the treatment of adult patients with relapsed / refractory multiple myeloma.

We are developing our off-the-shelf NK- iPSC-derived CAR NK cell and CAR T-cell product candidates for the treatment of cancer. cancer and autoimmune diseases. While we believe our use of clonal master proprietary iPSC lines for the production of product platform and our off-the-shelf, NK- and T-cell multiplexed-engineered, iPSC-derived cell product candidates is are highly differentiated, a number of clinical-stage companies are currently focused on the development of cellular immunotherapies for the treatment of cancer including Adaptimmune Therapeutics plc, and autoimmune diseases. These competitive companies include, among others, Allogene Therapeutics, Inc., Atara Biotherapeutics, Arcellx, Inc., AstraZeneca plc, Autolus Therapeutics plc, Bristol-Myers Squibb Company, Cabaletta Bio, Inc., CARGO Therapeutics, Inc., Caribou Biosciences, Inc., Cartesian Therapeutics, Inc., Cellectis SA, Celularity, Century Therapeutics, Inc., CRISPR Therapeutics AG, Gilead Sciences, Inc., Galapagos NV, ImmunityBio, Inc., Intellia Janssen Biotech (Johnson & Johnson), Legend

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Biotech Corporation, Kite Pharma (Gilead Sciences, Inc.), Kyverna Therapeutics, Inc., Iovance Biotherapeutics, Inc., Johnson & Johnson, Legend Biotech Corporation, Nkarta, Inc., Novartis AG, Precision Biosciences, Poseida Therapeutics, Inc., Sanofi SA, Sana Biotechnology, Inc. and Takeda Pharmaceutical Company Limited, and 2seventy bio, Inc. Limited. Preclinical-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We compete against our competitors in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and subject enrollment for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Many of our competitors, either alone or with their collaboration partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of treatments and commercializing those treatments. Accordingly, our competitors may be more successful than us in obtaining approval for treatments and achieving widespread market acceptance.

We anticipate that we will face intense and increasing competition as new products enter the market and advanced technologies become available. We expect any treatments that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price, the level of generic competition and the availability of reimbursement from government and other third-party payers. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, 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, which could result in our competitors establishing a strong market position before we are able to enter the market.

Insurance

We maintain product liability insurance for our clinical trials. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for products in development. However, insurance coverage is becoming increasingly expensive, and 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. In addition, we may not be able to obtain commercially reasonable product liability insurance for any products approved for marketing.

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Human Capital

Our success as a company depends upon the innovation, drive, and dedication of our employees, and we seek to attract, incentivize, and reward creative and performance-driven employees. We believe our commitment to our human capital resources is an important component of our business that enables us to deliver superior performance in our industry.

We focus on identifying, recruiting, developing and retaining a team of highly talented and motivated employees. As of December 31, 2022 December 31, 2023, we employed 551 181 employees, all of whom are full-time employees, including 238 82 in research and development, 212 49 in clinical development, manufacturing and regulatory affairs and 101 50 in general and administrative. We have never had a work stoppage, and none of our employees is represented by a labor organization or under any collective bargaining arrangements. We believe that our relationship with our employees is good, and we provide all employees with the opportunity to share their opinions in open dialogues with our human resources department

and senior management.

In January 2023, we implemented a corporate restructuring to streamline our operations, reduce our operating expenses, extend our cash runway and focus our resources on our most promising programs. In connection with the restructuring, we committed to a reduction in our total workforce by approximately 60%, to approximately 220 employees.

Equity, Diversity, and Inclusion

We believe that an equitable, diverse, and inclusive workforce is a necessary foundation for innovation and dedication of our employees. Accordingly, we strive to promote diversity, inclusion and equal opportunity across the organization. We are committed to actively seeking out highly qualified women and minority candidates, as well as candidates with diverse backgrounds, skills and experiences. As of January 6, 2023 December 31, 2023, women made up 53.4% 55% of our workforce and represented 42.9% 50% of leadership positions at the Director level director-level and above.

In addition, as of December 31, 2023, ethnic or racial minorities made up 54% of all of our employees, with 32% Asian, 12% Hispanic, 4% Black, 2% Native Hawaiian or other Pacific Islander and 4% of two or more races. Ethnic or racial minorities made up 43% of our director-level and above employees, with 35% Asian, 3% Hispanic, 3% Black, and 2% of two or more races. The age breakdown of our employee workforce consisted of 49% of employees between the ages of 25 – 39 years old, 45% of employees between the ages of 40 – 50 years old, and 6% of employees 55 and older.

Health and Safety

The success of our business is fundamentally connected to the well-being, health and safety of our employees, and we are committed to providing a safe, healthy and secure workplace for our employees. We have an environmental, health and safety program and several cross-functional committees to support our environmental, health and safety program. We routinely train and

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educate our employees on workplace safety and security and maintain various compliance programs to support this commitment. We routinely train and educate our employees on workplace safety and security. Early in the pandemic we formed a COVID-19 task force dedicated to monitoring ongoing developments and guidance issued by local, state and public health authorities. Our COVID-19 task force provides regular updates and recommendations to our executive team, and provides timely communication and training to our employee base about the various safety measures we have put into place to protect their health and wellbeing. We took proactive action early on, implementing site enhancements and risk protocols, instituting remote working arrangements and adjusting our sick leave policies, and in our effort to support the safe occupancy of our sites, reconfigured work and common spaces to allow for social distancing increased office cleaning protocols, instituted daily health screenings and COVID-19 testing. As testing has become more readily available, we have offered both onsite testing and memberships to local medical clinics that offer testing. We continue to monitor and adjust our safety training and protocols as needed to ensure the pandemic continues to evolve.safety and wellbeing of our workforce.

Compensation and Benefits

We offer competitive pay, with performance-based bonuses and equity awards. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives. We have a comprehensive benefits program offering flexibility for our employees' individual needs and requirements. Our benefits program includes a choice of medical plans, vision and dental coverage, flexible spending accounts for health and dependent day care needs, and income protection through life, AD&D, short term and long term disability coverage, sick leave, paid family leave, and generous paid time off. We offer a 401(k) retirement plan with company matching a percentage of employee contributions, an employee assistance program, and onsite fitness centers at no cost to our employees.

Employee Development and Engagement

We are focused on attracting and retaining a team of highly talented and motivated employees. We invest in and develop all levels of employees by engaging in ongoing career pathing and professional development conversations throughout an employee's tenure. In addition, we provide targeted leadership development programs for frontline leaders through executive leadership programs and offer a number of professional, management and leadership development training programs to help our employees develop cross-functional skills and tools to grow their careers.

Employees are incentivized for key contributions through awards programs that recognize their commitment and dedication by demonstrating our *Fate Pathways to Success*.

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We focus on identifying, recruiting, developing and retaining a team of highly talented and motivated employees. We believe that our relationship with our employees is good. We believe our commitment to our human capital resources is an important component of our business that enables us to deliver superior performance in our industry. We provide all employees with the opportunity to share their opinions in open dialogues with our human resources department and senior management. We provide all employees a wide range of professional development experiences, both formal and informal. The safety and wellbeing of our employees is a paramount value for us. Further, the health and wellness of our employees are critical to our success. We provide our employees with access to a variety of flexible and convenient health and wellness programs. Such programs are designed to support employees' employees' physical and mental health by providing tools and resources to help them improve or maintain their health status and encourage engagement in healthy behaviors. Additionally, we provide competitive compensation and benefits. In addition to salaries, these programs can include annual bonuses, stock-based compensation awards, a 401(k) plan with employee matching opportunities, healthcare and insurance benefits, health savings and flexible spending accounts, paid time off, family leave, and family care resources.

Environmental Sustainability

We recognize the importance of the environment to a healthy, sustainable future for our business, our patients, and communities. Our headquarters located in San Diego, California was designed to be energy efficient through the use of LED lighting, energy efficient air handling units, a fully integrated building management system, and other tools. Our facilities are also outfitted with smart building solutions, such as occupancy sensors and air conditioning units reducing airflow based on occupancy. Water-saving bathroom faucets and toilets are installed throughout the building to help reduce water consumption. The exterior of our building is made up of draught tolerant landscaping to reduce the volume of water needed to maintain plant life around the building. Employees are also provided free access to electric vehicle charging stations. Our commitment to environmental sustainability is ongoing and we continue to be mindful of how we can minimize our environmental footprint as a company.

Corporate Information

We were incorporated in Delaware in 2007, and are headquartered in San Diego, CA. California. Our principal executive office is located at 12278 Scripps Summit Drive, San Diego, California 92131, and our telephone number is (858) 875-1800. Our website address is www.fatetherapeutics.com. We do not incorporate the information on or accessible through our website into this Annual Report on Form 10-K, and you should not consider any information on, or that can be accessed through, our website a part of this Annual Report on Form 10-K.

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We own various U.S. federal trademark registrations and applications, and unregistered trademarks, including Fate Therapeutics®, our corporate logo. All other trademarks or trade names referred to in this document are the property of their respective owners. Solely for convenience, the trademarks and trade names in this document are referred to without the symbols® and ™, 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.

Available Information

We post our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, on the Investors section of our public website (www.fatetherapeutics.com) as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. In addition, you can read our SEC filings over the Internet at the SEC's website at www.sec.gov. You can access these filings on our website or from the SEC free of charge. The contents of these websites are not incorporated into this Annual Report on Form 10-K. Further, our references to the URLs for these websites are intended to be inactive textual references only.

Item 1A. Risk Factors

You should carefully consider the following risk factors, as well as the other information in this Annual Report on Form 10-K, and in our other public filings. The occurrence of any of these risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described in our public filings when evaluating our business.

Risks Related to Our Financial Condition

Our ongoing and planned operations, including the development of our product candidates, will require substantial additional funding, without which we will be unable to complete preclinical or clinical development of, or obtain regulatory approval for, or commercialization of our product candidates.

We are currently advancing multiple product candidates through clinical development, and conducting preclinical research and development activities in other programs. Drug development is expensive, and we expect our research and development expenses to remain significant in connection with our ongoing activities, particularly as we advance our current product candidates in clinical trials and seek to initiate clinical development for additional product candidates.

As of December 31, 2023, our cash and cash equivalents and investments were $316.2 million. We intend to use our cash and cash equivalents and investments primarily to fund the advancement and clinical development of our current product candidates and our ongoing preclinical, discovery and research programs, and for working capital and general corporate purposes. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic and licensing arrangements or a combination of these approaches. In any event, we will require additional capital to obtain regulatory approval for, and to commercialize our existing product candidates and any other product candidates we may identify and develop. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Our future capital requirements will depend on many factors, including, but not limited to:

- the progress, results, size, timing and costs of our ongoing and planned clinical trials, and any additional clinical trials we may initiate, conduct or support for our product candidates;
- the progress, results, size, timing and costs of our preclinical, process development and manufacturing studies, and activities necessary to initiate and conduct clinical trials for our product candidates and to establish and maintain manufacturing capabilities necessary to support such trials;
- continued progress in our research and development programs, including preclinical studies, process development, manufacturing and other research activities that may be necessary in order for an IND application to go into effect for a prospective clinical development candidate, as well as potential future clinical trials of any additional product candidates we may identify for development;
- the extent to which we are required to pay milestone or other payments under our existing in-license agreements and any in-license agreements that we may enter into in the future, and the timing of such payments, including payments owed to MSKCC in connection with the stock price appreciation milestones;

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- our ability and the ability of our investigators to initiate and conduct, and the progress, results, size, timing and costs of, clinical trials of our product candidates that will be necessary to support any application for regulatory approval;
- our ability to manufacture, or enter into arrangements with third parties for the manufacture of our existing product candidates, as well as potential future clinical development candidates, both for clinical development and commercialization, and the timing and costs associated with such manufacture;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, or other costs we may incur, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the cost of manufacturing, distribution, and commercialization activities and arrangements, including the manufacturing of our product candidates, establishment of effective protocols for the supply and transport of our product candidates, and the establishment of a sales and marketing organization either internally or in partnership with a third party; and
- our ability to establish and maintain strategic arrangements and alliances with third-party collaborators including our existing collaborations with Ono, the University of Minnesota, and MSKCC, to advance the research, development and commercialization of therapeutic products.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment and interest obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to

conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at a different stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. In addition, while the overall impacts of the ongoing wars between Russia and Ukraine and between Israel and Hamas on the global economy remain unknown and difficult to predict, these events caused significant disruptions and created uncertainties in the global financial markets, and the economic impacts of these and other similar global events could materially and adversely affect our ability to raise capital through equity or debt financings in the future.

If we cannot raise additional capital or obtain adequate funds, we may be required to curtail significantly our research and clinical programs or may not be able to continue our research or clinical development of our product candidates. Our failure to raise additional capital, or obtain adequate funds, will have a material adverse effect on our business, prospects, financial condition, results of operations, and market price of shares of our common stock.

We have a limited operating history, have incurred significant losses since our inception, and anticipate that we will continue to incur significant losses for the foreseeable future.

We are a clinical-stage biopharmaceutical company formed in 2007 with a limited operating history. We have not yet obtained regulatory approval for any of our product candidates or generated any revenues from therapeutic product sales. Since inception, we have incurred significant net losses in each year and, as of December 31, 2023, we had an accumulated deficit of $1.2 billion. We expect to continue to incur losses for the foreseeable future as we continue to fund our ongoing and planned clinical trials of our product candidates, and our other ongoing and planned research and development activities. We also expect to incur significant operating and capital expenditures as we continue our research and development of, and seek regulatory approval for, our product candidates, in-license or acquire new product candidates for development, implement additional infrastructure and internal systems, and hire additional scientific, clinical, and administrative personnel. We anticipate that our net losses for the next several years could be significant as we conduct our planned operations.

Because of the numerous risks and uncertainties associated with pharmaceutical, biological, and cell therapy product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. In addition, our expenses could increase if we are required by the FDA, or comparable foreign regulatory authorities, to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical trials, preclinical studies, process development, manufacturing activities, or the research and development of any of our product candidates. The amount of our future net losses will depend, in part, on the rate of increase in our expenses, our ability to generate revenues and our ability to raise additional capital. These net losses have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

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We have broad discretion over the use of our cash, cash equivalents, and investments and may not use them effectively.

Our management has broad discretion to use our cash, cash equivalents, investments and any additional funds that we may raise to fund our operations and could spend these funds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline or delay the development of our product candidates. We may invest our cash and cash equivalents in a manner that does not produce income or that loses value.

Risks Related to the Discovery, Development and Regulation of Our Product Candidates

If we fail to complete the preclinical or clinical development of, or to obtain regulatory approval for, our product candidates, our business would be significantly harmed.

All of our product candidates are currently in research or early clinical development. We have not completed clinical development of or obtained regulatory approval for any of our product candidates. Only a small percentage of research and development programs ultimately result in commercially successful products, and we cannot assure you that any of our product candidates will demonstrate the safety, purity and potency, or efficacy profiles necessary to support further preclinical study, clinical development or regulatory approval.

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We may delay experience delays in, or cancel our ongoing and planned clinical development activities or research and development activities for any of our product candidates for a variety of reasons, including:

- difficulties in optimizing the right dose and dosing schedule for our product candidates, which might result in a determination that a product candidate is ineffective, causes harmful side effects, or otherwise presents unacceptable safety risks during clinical trials or has an unfavorable toxicity profile in preclinical studies to support clinical investigation;
- difficulties in manufacturing or distributing a product candidate, including the inability to manufacture and distribute a product candidate in a sufficient quantity, suitable form, or in a cost-effective manner, or under protocols and processes and with materials and facilities acceptable to the FDA for the conduct of clinical trials or for marketing approval;
- our prioritization of other certain of our product candidates for advancement or the emergence of competing product candidates developed by others, including a decision to cease research and development of any existing product candidate due to the potential obsolescence of our product candidate by a competing product or product candidate or our determination that another of our existing or future product candidates has greater potential for clinical development, regulatory approval, or commercialization, including potentially greater therapeutic benefit, a more favorable safety or efficacy profile, a more consistent or more cost effective manufacturing process, or more a favorable commercial profile, including greater market acceptance or commercial potential, or more advantageous intellectual property position;
- challenges and delays in trial execution associated with our testing of multiple product candidates in the same indication in different clinical trials, as well as competition from biotechnology and pharmaceutical companies, universities, and other research institutions for patients and clinical trial sites;
- the proprietary rights of third parties, which may preclude us from developing, manufacturing or commercializing a product candidate;
- determining that a product candidate may be uneconomical to develop, manufacture, or commercialize, or may fail to achieve market acceptance or an adequate pricing and reimbursement profile;
- our inability to secure or maintain relationships with strategic partners that may be necessary for advancement of a product candidate into or through clinical development, regulatory approval and commercialization in any particular indication(s) or geographic territory(ies); or and
- difficulty establishing predictive preclinical models for demonstration of safety and efficacy of a product candidate in one or more potential therapeutic areas for clinical development.

For example, in January 2023, we announced the discontinuation of our FT516, FT596, FT538, and FT536 NK cell programs to focus our resources on advancing our most innovative and differentiated programs. We also announced the termination of our Collaboration and Option Agreement with Janssen, which will take took effect on April 3, 2023. As a result of the termination, we will wind down all performed wind-down activities for the collaboration activities in the first quarter of 2023, including winding down the development of two product candidates that were had been expected to enter the clinic in 2023.

Additionally, we will only be able to obtain regulatory approval to market a product candidate if we can demonstrate, to the satisfaction of the FDA or comparable foreign regulatory authorities, in well-designed and conducted clinical trials that such product candidate is manufactured in accordance with applicable regulatory requirements, is safe, pure and potent, or effective, and otherwise meets the appropriate standards required for approval for a particular indication. Our ability to obtain regulatory approval of our product candidates depends on, among other things, completion of additional preclinical studies, process development and manufacturing activities, and clinical trials, whether our clinical trials demonstrate statistically significant efficacy with safety profiles that do not potentially outweigh the therapeutic benefit, and whether regulatory agencies agree that the data from our clinical trials and our manufacturing operations are sufficient to support approval. In addition, the approval by the FDA of new products in the same indications that we are studying may change the standard of care, and this may result in the FDA or other regulatory agencies requesting that we conduct additional studies to show that our product candidate is superior to the new standard of care. Securing regulatory approval also requires the submission of information about product manufacturing operations to, and inspection of manufacturing facilities by, the relevant regulatory authority. The results of our current and future clinical trials may not meet the FDA's or other regulatory agencies' requirements to approve a product candidate for marketing, and the regulatory agencies may otherwise determine that our manufacturing operations are insufficient to support approval. We may need to conduct preclinical studies and clinical trials that we currently do not anticipate, including as a result of changes in the standard of care. If we fail to complete preclinical or clinical development of, or obtain regulatory approval for, our product candidates, we will not be able to generate any revenues from product sales and our ability to receive milestone or other payments under any collaboration agreements may be impaired, which will harm our business, prospects, financial condition and results of operations.

We may face delays in initiating, conducting or completing our clinical trials, and we may not be able to initiate, conduct or complete them at all.

We are heavily dependent on our ability to complete the clinical development of, and obtain regulatory approval for, our product candidates. We have not completed the clinical trials necessary to support an application for approval to market any of our product candidates. We, or any investigators who initiate or conduct clinical trials of our product candidates, may experience delays in our current or future clinical trials, and we do not know whether we or our investigators will be able to initiate, enroll patients in, or complete, clinical trials of our product candidates on time, if at all. Current and future clinical trials of our product candidates may be delayed, unsuccessful or terminated, or not initiated at all, as a result of many factors, including factors related to:

- difficulties in identifying eligible patients for participation in clinical trials of our product candidates, due in part to our focus on the development of certain of our product candidates for the treatment of rare diseases;
- difficulties enrolling a sufficient number of suitable patients to conduct clinical trials of our product candidates, including difficulties resulting from patients enrolling in studies of therapeutic product candidates sponsored by us or our competitors and difficulties resulting from patient availability as a result of mandated travel restrictions, prioritization of hospital and other medical resources toward pandemic efforts, policies and procedures implemented at clinical sites with respect to the conduct of clinical trials, and other precautionary any measures taken in treating patients by governmental authorities, hospitals, or in practicing medicine clinical trial sites in response to the ongoing COVID-19 pandemic; any future public health crises or other serious disasters or similar events;
- difficulties determining suitable doses and schedules of our novel cell product candidates for evaluation in clinical trials;
- difficulties in obtaining agreement from regulatory authorities on study endpoints and/or study duration, achieving study endpoints, the amount and sufficiency of data demonstrating efficacy and safety, and completing data analysis in clinical trials for any of our product candidates;
- delays in filing an IND application or IND amendment with the FDA to initiate or amend clinical trials of our current product candidates and any other product candidates that we may identify;
- difficulties in obtaining agreement from regulatory authorities on the preclinical safety and efficacy data, the manufacturing requirements, and the clinical trial design and parameters necessary for an IND application to go into effect to initiate and conduct clinical trials for any of our current product candidates and any other product candidates that we may identify; develop;
- the occurrence of unexpected safety issues or adverse events in any ongoing or future clinical trials of our product candidates, including in trials of our product candidates conducted by investigator-sponsors;
- securing and maintaining the support of clinical investigators and investigational sites, including investigators and sites who may conduct clinical trials under an investigator-sponsored IND with our financial support, and obtaining institutional review board (IRB) approval at each site for the conduct of our clinical trials;
- reaching agreement on acceptable terms with third-party service providers and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different service providers and clinical trial sites;

- failure by us or third parties that we contract with, to manufacture certain of our product candidates consistently, and in sufficient quantities, at acceptable quality levels and costs, in accordance with our protocol-specified manufacturing requirements and applicable regulatory requirements;
- failure or delays in obtaining sufficient quantities of suitable raw materials, components, and equipment necessary for the conduct of our clinical trials or the manufacture of any product candidate, including any inability to obtain materials as a result of supply chain issues related to the COVID-19 pandemic and any future public health crises or other serious disasters or the ongoing conflict in Ukraine; wars between Russia and Ukraine and between Israel and Hamas, or other factors;
- failure or delays by us or by our clinical sites to obtain sufficient quantities of components and supplies necessary for the conduct of our clinical trials, including any inability to obtain agents such as cyclophosphamide or fludarabine which are often required to condition patients for treatment with our product candidates, or certain monoclonal antibodies which are intended for administration to patients in combination with many of our product candidates in certain of our clinical trials;
- challenges in distributing our product candidates to clinical trial sites, or failure to establish effective protocols for the supply and transport of our product candidates;
- the costs of conducting clinical trials or manufacturing of our product candidates being greater than we anticipate, including due to rising inflation rates, or the timelines for these activities being longer than we anticipate;

- our failure, or the failure of investigators, third-party service providers, or clinical trial sites, to ensure the proper and timely conduct of and analysis of data from clinical trials of our product candidates;
- inability to reach agreement on clinical trial design and parameters with regulatory authorities, investigators, and IRBs;

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- regulatory authorities or data monitoring committees requiring or recommending suspension, termination or a clinical hold for various reasons, including concerns about patient safety or the safety of novel therapeutics derived from pluripotent or genome edited therapies;
- the serious, life-threatening diseases of the patients enrolled in our oncology clinical trials, who may die or suffer adverse medical events during the course of the trials for reasons that may not be related to our product candidates;
- failure of patients to complete clinical trials or adhere to study protocols due to safety issues, side effects, disruptions in study conduct, including study monitoring, data collection and analysis, restrictions on hospital visits or travel relating to the COVID-19 pandemic, or other reasons;
- approval of competitive agents that may materially alter the standard of care on which a clinical development plan was based, which may require new or additional trials, or render our product candidates or clinical trial designs obsolete;
- governmental or regulatory delays, including any delays due to limitations on the availability of governmental and regulatory agency personnel to review regulatory filings, conduct site inspections or engage in discussions with us as a result of the ongoing COVID-19 pandemic, any future public health crisis or other serious disaster or similar events, failure to obtain regulatory approval, or uncertainty or changes in U.S. or foreign regulatory requirements, policy or guidelines; and
- limitations on clinical trial conduct at our clinical trial sites resulting from prioritization of hospital and other medical resources toward other efforts, such as the COVID-19 pandemic any future public health crisis or other public health concerns, serious disaster or similar events, policies and procedures implemented at clinical sites with respect to the conduct of clinical trials including those relating to site initiation, study monitoring, and data collection and analysis, and other precautionary measures taken in treating patients or in practicing medicine in response to various public health concerns.

If there are delays in initiating or conducting any clinical trials of our product candidates or any of these clinical trials are terminated before completion, the commercial prospects of our product candidates will be harmed. In addition, any delays in initiating, conducting or completing our clinical trials or adjustments to certain of our study protocols and procedures, including as a result of any shortage of materials or agents necessary to conduct our studies or as a result of the COVID-19 pandemic any future public health crisis or other public health concerns or other factors, will increase our costs, slow down our product candidate development and regulatory approval process, and jeopardize our ability to gain regulatory approval, commence product sales and generate revenues. Furthermore, many of the factors that cause, or lead to, a delay in the initiation, conduct or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Any of these occurrences would significantly harm our business, prospects, financial condition, results of operations, and market price of shares of our common stock.

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The manufacture and distribution of our cell product candidates, particularly our iPSC-derived cell product candidates, is complex and subject to a multitude of risks. These risks could substantially increase our costs and limit the clinical and commercial supply of our product candidates, and the development and commercialization of our product candidates could be substantially delayed or restricted if the FDA or other regulatory authorities impose additional requirements on our manufacturing operations or if we are required to change our manufacturing operations to comply with regulatory requirements.

The manufacture and supply of our cell product candidates involve involves novel processes that are more complex than those required for most small molecule drugs and other cellular immunotherapies, and accordingly present significant challenges and are subject to multiple risks. For our iPSC-derived product candidates, these complex processes include reprogramming human fibroblasts to obtain iPSCs, in some cases genetically engineering these iPSCs, and differentiating the iPSCs to obtain the desired cell product candidate. As a result of the complexities in manufacturing biologics and distributing cell therapies, the cost to manufacture and distribute biologics and cell therapies in general, and our cell product candidates in particular, is generally higher than for traditional small molecule chemical compounds. In addition, our cost of goods development is at an early stage. The actual cost to manufacture and process our product candidates could be greater than we expect and could materially and adversely affect the commercial viability of our product candidates.

We have limited experience in the manufacture of cell-based therapies. We are still developing optimized and reproducible manufacturing processes for clinical and commercial-scale manufacturing of our product candidates, and none of our manufacturing processes have been validated for commercial production of our product candidates. We may face multiple challenges as we scale our manufacturing for large-scale clinical trials or commercial-scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance

with good manufacturing practices, lot consistency and timely availability of raw materials. In addition, we are continuing to optimize our protocols for the supply and transport of our product candidates for distribution to clinical trial sites. Although we are working to develop reproducible and commercially viable manufacturing processes for our product candidates, and effective protocols for the supply and transport of our product candidates, doing so is a difficult and uncertain task.

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We may make changes or be required by the FDA to make changes to our manufacturing processes, including materials and equipment used in manufacturing our product candidates, as we continue to develop and refine the manufacturing and distribution processes for our product candidates for advanced clinical trials and commercialization, and we cannot be sure that even minor changes in these processes, materials, and equipment will not cause our product candidates to perform differently and affect the results of our ongoing and planned clinical trials or the performance of the product once commercialized. In some circumstances, changes in our manufacturing operations, including to our protocols, processes, materials or facilities used, may require us to perform additional preclinical or comparability studies, or to collect additional clinical data from patients prior to undertaking additional clinical studies or filing for regulatory approval for a product candidate. These requirements may lead to delays in our clinical development and commercialization plans for our product candidates, and may increase our development costs substantially.

The manufacturing processes for any products that we may develop are subject to FDA and foreign regulatory authority approval requirements, and we will need to meet, and our CMOs any contract manufacturing organizations (CMOs) or other third party manufacturers that we may engage for manufacturing our product candidates, will need to meet, all applicable FDA and foreign regulatory authority requirements on an ongoing basis. Our existing product candidates are currently manufactured by us or by third-party cell processing facilities or CMOs, including facilities operated by or affiliated with our clinical sites, and our current manufacturing operations, including protocols, processes, materials, and facilities, may not support regulatory approval of our existing product candidates. We may be required to identify alternative protocols, processes, materials or facilities for the manufacture of any of these product candidates in compliance with applicable regulatory requirements. In addition, we may be required to make changes to our protocols for the supply and transport of our product candidates to enable effective distribution of our product candidates. Any modifications to our manufacturing and supply protocols, processes, materials or facilities, and any delays in, or inability to, establish acceptable manufacturing and supply operations for our product candidates could require us to incur additional development costs or result in delays to our clinical development. If we or our any CMOs or other third-party manufacturers that we may engage for manufacturing our product candidates are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the regulatory approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our any CMOs or other third-party manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities and on the requisite timelines to meet the requirements for the potential launch of the product, or to meet potential future demand. Additionally, changes in regulatory requirements may require us or our any third-party manufacturers to perform additional studies or to modify protocols, processes, materials or facilities for the manufacture of our product candidates or any components thereof. Any of these challenges could delay initiation or completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and prospects.

A variety of risks associated with conducting research and clinical trials abroad and marketing our product candidates internationally could materially adversely affect our business. 41

We plan to develop and potentially commercialize our product candidates worldwide. Accordingly, we expect that we will be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- increased difficulties in managing the logistics and transportation of storing and shipping product candidates produced in the U.S. and shipping the product candidate to the patient abroad;
- import and export requirements and restrictions;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing

business in another country;

- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems, and price controls;
- potential liability under the FCPA or comparable foreign regulations;

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- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, such as the ongoing conflict in Ukraine.

These and other risks associated with our potential international operations may materially adversely affect our ability to attain or maintain profitable operations, which could have a material adverse effect on our business and results of operations.

We plan to conduct clinical trials for our product candidates outside the United States, and the FDA may not accept data from trials conducted in such locations.

To date, we have only conducted clinical trials in the United States. However, we may in the future choose to conduct one or more of our clinical trials or include sites in current or future clinical trials outside the United States.

Although the FDA may accept data from sites or clinical trials outside the United States, acceptance of these data is subject to conditions imposed by the FDA. The FDA will generally not consider the data from a foreign clinical trial not conducted under an IND unless (i) the trial was well-designed and well-conducted in accordance with GCP requirements, including requirements for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials in a way that provides assurance that the data and reported results are credible and accurate and that the rights, safety, and well-being of trial subjects are protected, and (ii) the FDA is able to validate the data from the trial through an onsite inspection, if necessary. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such as inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering must be met. Many foreign regulatory authorities have similar approval requirements. In addition, while these clinical trials or trial sites are subject to the applicable local laws where the trials are conducted, FDA acceptance of the data will depend on its determination that the trials or trial sites also complied with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside the United States. If the FDA does not accept the data from any trial or trial site outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and would delay or halt our development of the applicable product candidates.

A disruption to our manufacturing operations, or our the inability by us or our third-party suppliers' suppliers or manufacturers' inability manufacturers to manufacture sufficient quantities of our product candidates at acceptable quality levels or costs, or at all, would materially and adversely affect our business.

Developing manufacturing processes to support clinical studies and commercialization requirements is a difficult and uncertain task, and there are risks associated with scaling to the level required for clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale-out, process reproducibility, stability and purity issues, lot consistency, and timely availability of acceptable reagents and raw materials. If we are unable to scale to the level required for the conduct of clinical trials or commercialization, we may not be able to produce our product candidates in a sufficient quantity to conduct our ongoing and planned clinical trials, or to meet demand if any product candidates are approved for commercialization. We have not yet caused any of our product candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our product candidates.

We are substantially dependent on our own internal manufacturing facilities in San Diego, California for the production of our product candidates, and we rely, and expect to may continue to rely, on third parties for the manufacture of certain components to manufacture our product candidates for use in conducting clinical trials. The facilities used to manufacture our product candidates, including our own facilities, must be evaluated by the FDA or other foreign regulatory agencies pursuant to inspections that will be conducted after we submit an application to the FDA or other foreign regulatory agencies. If the FDA or a comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it later finds deficiencies or withdraws any such approval in the future, we may not be able to locate additional or replacement facilities to produce such product candidates or materials in a timely manner and on commercially reasonable terms, or at all. This would significantly

impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Because we rely on our own manufacturing facilities to produce our product candidates and on third parties for the manufacture of certain components, we are required to transfer certain manufacturing process know-how and certain intermediates to third parties, including larger-scale facilities operated by a CMO or by us, to facilitate manufacture of our product candidates for clinical trials and

commercialization. Transferring manufacturing testing and processes and know-how is complex and involves review and incorporation of both documented and undocumented processes that may have evolved over time. In addition, transferring production to different facilities may require utilization of new or different processes to meet the specific requirements of a given facility. We and any CMOs or third parties that we engage to manufacture our product candidates will need to conduct significant development work to transfer these processes and manufacture each of our product candidates for clinical trials and commercialization. In addition, we may be required to demonstrate the comparability of material generated by any CMO or third parties that we engage for manufacturing our product candidates with material previously produced and used in testing. Any inability to manufacture comparable drug product by us or any CMOs or third parties that we engage to manufacture our CMOs product candidates could delay the continued development of our product candidates.

In addition to relying on third parties for the manufacture of certain components for the manufacture of our product candidates, we manufacture our product candidates ourselves, and intend to manufacture some or all of the clinical supply of our iPSC-derived NK-cell and T-cell product candidates for our ongoing and planned clinical trials. To do so, we will need to scale up our own manufacturing operations, as we do not currently have the infrastructure or capability internally to manufacture sufficient quantities of each of our product candidates to support the conduct of each of our clinical trials or commercialization of each of our product candidates, if approved. Accordingly, we will be required to make significant investments to maintain and expand our existing GMP Good Manufacturing Practice (GMP) manufacturing capabilities and facilities, establish additional GMP manufacturing facilities, conduct GMP production, and process and scale up development and technology transfer activities for the manufacture of our product candidates, and our efforts to scale our own manufacturing operations may not succeed.

Even if we are successful in developing manufacturing capabilities sufficient for clinical and commercial supply, problems with our manufacturing operations or those of the third-party manufacturers upon which we rely, including difficulties with production costs and yields, quality control, stability of the product, quality assurance testing, operator error, shortages of qualified personnel, shortages of materials and supplies, facility shutdowns, due to the ongoing COVID-19 pandemic global pandemics or other public health concerns, war or armed conflicts such as the ongoing conflict in wars between Russia and Ukraine and between Israel and Hamas, natural disasters (including due to the effects of climate change) or other reasons, as well as compliance with strictly enforced federal, state and foreign regulations, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims or insufficient supplies of our product candidates for our ongoing and planned clinical trials or eventual commercialization. Further, delays in regulatory inspections, commissioning and receiving regulatory approvals for our manufacturing capabilities or facilities, including any new facilities as a result of limited governmental resources due to the COVID-19 pandemic or otherwise, could delay our development plans, including the initiation and conduct of our ongoing and planned clinical trials. In addition, we and our third-party manufacturers may have limited manufacturing capacity for certain product candidates or components used in manufacturing our product candidates, and we may fail to locate suitable additional or replacement manufacturing capacity, including for the manufacture of our product candidates in compliance with cGMP current GMP (cGMP) or cGTP, current Good Tissue Practice (cGTP), on a reasonable basis or at all. Any such failure could be the basis for the FDA to issue a warning letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure of outside supplies of the product candidate, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending

applications or supplemental applications, detention of product, refusal to permit the import or export of products, injunction or imposing civil and criminal penalties.

Furthermore, certain of the components currently used in manufacturing our product candidates are research-grade only, and we may encounter problems obtaining or achieving adequate quantities and quality of clinical grade materials that meet FDA, European Medicines Agency, or other applicable standards or specifications with consistent and acceptable production yields and costs. In addition, if contaminants are discovered in our supply of product candidates or in our manufacturing facilities or those of our third-party suppliers and manufacturers, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Any such events could delay or prevent our ability to

obtain regulatory approval for or commercialize our product candidates, which would adversely affect our business, prospects, financial condition and results of operations.

Because our approach to the development of product candidates is based on novel and unproven technologies, it is subject to a substantial degree of technological uncertainty and we may not succeed in developing any of our product candidates.

All of our current product candidates are based on our novel iPSC platform, and some of our product candidates utilize novel genome editing technologies. To date, no iPSC-derived therapeutic product candidates have been approved in the United States or worldwide, and there have been only a limited number of regulatory approvals of genome edited therapeutics, and similarly a limited number of clinical trials involving the use of a therapeutic product candidate manufactured using a master iPSC line or genome edited cells. The development of such complex cell therapies is a relatively new and emerging field, and the scientific research that forms the basis of our efforts to discover and develop iPSC-derived and genome edited cellular immunotherapies is ongoing. We may determine to incorporate information learned from this research into the design of our ongoing Phase 1 clinical trials of our iPSC product candidates, as well as our planned future clinical trials, which could delay or impair our clinical development activities. We may ultimately discover that our product candidates do not possess certain properties required for therapeutic effectiveness or protection from toxicity in our target patient populations, or they may exhibit undesirable side effects as more patient data become available. In addition, our product candidates may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies. It may take many years before we develop a full understanding of the pharmacological properties of our product

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candidates, and we may never know precisely how they function *in vivo*. Moreover, our genome editing approach may cause unintended changes to the DNA such as a non-target site gene editing, a large deletion or a DNA translocation, any of which could lead to oncogenesis or other adverse effects. As with any new biologic or product developed using novel technologies, our product candidates have an unknown immunogenicity profile. As a result, our cellular immunotherapy product candidates may trigger immune responses that inhibit their therapeutic effects or cause adverse side effects. In addition, one or more of our product candidates may:

- be found ineffective or cause harmful side effects during preclinical studies or clinical trials;
- fail to receive necessary regulatory approvals on a timely basis or at all;
- be precluded from commercialization by proprietary rights of third parties;
- be difficult to manufacture on a large scale; or
- be uneconomical to commercialize or fail to achieve market acceptance.

Any such problems that affect one of our product candidates may have an unfavorable impact on all of our product candidates. As a result, we may never succeed in developing a marketable product and we may never become profitable, which would have an adverse effect on our business, prospects, financial condition, results of operations, and market price of shares of our common stock.

We anticipate that our current product candidates and any future product candidates may be used in combination with third-party drugs or biologics, some of which may still be in development, and we have limited or no control over the supply, regulatory status, or regulatory approval of such drugs or biologics.

Certain of our product candidates are being developed for use in combination with one or more other cancer therapies, such as monoclonal antibodies, and other current or future product candidates may be used in combination with other biologics or drugs, both approved and unapproved, such as fludarabine. Our ability to develop and ultimately commercialize our current product candidates and any future product candidates used in combination with another drug or biologic will depend on our ability, or the ability of third-party clinical trial sites on which we rely, to access such drugs or biologics on commercially reasonable terms for the clinical trials and their availability for use with the commercialized product, if approved. We cannot be certain that we, or third-party clinical trial sites on which we rely, will be able to secure a steady supply of such drugs or biologics on commercially reasonable terms or at all.

Any failure by us, or by third-party clinical trial sites on which we rely, to secure a steady supply of such drugs or biologics may delay our development timelines, increase our costs and jeopardize our ability to develop our current product candidates and any future product candidates as commercially viable therapies. If any of these occur, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. For example, the FDA or comparable foreign regulatory authorities may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of such trials could show that any positive previous trial results are attributable to the combination therapy and not our current product candidates and any future product candidates. Moreover, following product approval, the FDA or comparable foreign regulatory authorities may require that products used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to the other product, this may require us to work with a third party to satisfy such a requirement. Moreover, developments related to the other product may impact our clinical trials for the combination as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the other product's safety or efficacy profile, changes to the availability of the approved product, quality, manufacturing and supply issues, and changes to the standard of care.

In the event that any collaborator or supplier cannot continue to supply their products on commercially reasonable terms, we would need to identify alternatives for accessing such products. Additionally, should the supply of products from any collaborator or supplier be interrupted, delayed or otherwise be unavailable, our clinical trials may be delayed. In the event we are unable to source an alternative supply or are unable to do so on commercially reasonable terms, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

In addition, to the extent a third-party clinical trial site on which we rely sources a combination therapy itself and does not submit the costs of such therapy to government programs or patients' insurance, the costs of such therapy may be passed on to us, which could harm our business, financial condition, results of operations, stock price and prospects.

If we encounter difficulties enrolling patients in our clinical trials, including as a result of competition for patients, our clinical development activities could be delayed or otherwise adversely affected.

We are required to identify and enroll a sufficient number of patients with the disease under investigation for each of our ongoing and planned clinical trials of our product candidates, and we may not be able to identify and enroll a sufficient number of patients, or those with required or desired characteristics and who meet certain criteria, in a timely manner. In addition, we will be competing with other clinical trials of product candidates being developed by our competitors in the same therapeutic areas, and potential patients who might be eligible for enrollment in one of our clinical trials may instead choose to enroll in a trial being conducted by one of our competitors.

Our ability, and the ability of investigators, to enroll patients in our ongoing and planned clinical trials of our product candidates is affected by factors including:

- the ability to identify, solicit and recruit a sufficient number of patients;
- severity of the disease under investigation;
- design of the trial protocol;
- the relatively small size and nature of the patient populations for certain of our clinical trials;
- eligibility criteria for the trials in question;
- perceived clinicians' and patients' perceptions as to the potential risks and benefits of the product candidate under study, including any perceived risks associated with our iPSC-derived product candidates, which we believe are the first ever iPSC-derived cell therapies cleared by the FDA for clinical investigation in the United States; States, or with CAR T-cell therapies broadly following FDA's investigation into reports of T-cell malignancies for BCMA- and CD19-directed CAR T-cell therapies;
- the availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- the availability of time and resources at the limited number of institutions at which our clinical trials are or will be conducted, including any constraints on resources, or policies and procedures implemented, at hospitals and clinical trial sites as a result of the COVID-19 pandemic or other infectious diseases; any public health crisis;
- the availability of cells suitable for the manufacture of our clinical product candidates from eligible and qualified donors for certain of our product candidates;
- the availability of components and agents necessary to enroll and treat prospective patients in our clinical trials, including agents such as cyclophosphamide and fludarabine which are often required to condition patients and the latter of which is reported to be in short supply in the United States and worldwide, or monoclonal antibodies which are intended for administration to patients in combination with our product candidates, in certain of our clinical trials;

- the ability to monitor patients adequately during and after treatment, including through remote monitoring if required as a result of precautionary changes implemented at certain clinical trial sites as a result of the COVID-19 pandemic; any public health crisis; and

- the proximity and availability of clinical trial sites for prospective patients.

Moreover, development of certain of our product candidates as treatment for autoimmune diseases represents a novel approach where B cells may play a role in initiating or maintaining disease treatment, and potential patients and their doctors may choose to use conventional therapies, such as corticosteroids or systemic immunosuppressive medications, rather than enroll patients in our clinical trials.

In addition, certain of our clinical trial sites at times have delayed or paused patient enrollment in clinical trials as a result of the COVID-19 pandemic and supply chain shortages, and quarantines or other travel limitations relating to may do so again in the COVID-19 pandemic may impede patient movement and affect access to study sites, which may further impact patient enrollment in our clinical trials. future for a variety of reasons. The extent and duration of such delays and disruptions, and the overall impact on the timing and conduct of our clinical trials, are uncertain. If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay or terminate ongoing or planned clinical trials, either of which would have an adverse effect on our business, prospects, financial condition, results of operations, and market price of shares of our common stock.

The clinical development of our product candidates could be substantially delayed if we are required to conduct unanticipated studies, including preclinical studies or clinical trials, or if the FDA imposes other requirements or restrictions including on the manufacture, of our product candidates.

The FDA may require us to generate additional preclinical, product, manufacturing, or clinical data as a condition to continuing our current clinical trials, or initiating and conducting any future clinical trials of our current product candidates or other cell product candidates that we may identify. Additionally, the FDA may in the future have comments, or impose requirements, on the conduct of our clinical trials or the initiation of clinical trials or any of our other iPSC-derived cell product candidates, including the protocols, processes, materials and facilities we use to manufacture our product candidates and potential future product candidates in support of clinical trials. Any requirements to generate additional data, or redesign or modify our protocols, processes, materials or facilities, or other additional comments, requirements or impositions by the FDA, may cause delays in the initiation or conduct of the current or future clinical trials for our product candidates and subsequent development activities for our product candidates, and could require us to incur additional development or manufacturing costs and resources, seek funding for these increased costs or resources or delay our timeline for, or cease, our preclinical or clinical development activities for our product candidates, or could create uncertainty and additional complexity in our ability to obtain regulatory approval for our product candidates.

Further, if the results of our clinical trials are inconclusive, or if there are safety concerns or adverse events associated with our existing product candidates or any other product candidates we may identify, we may:

- be delayed in obtaining, or unable to obtain, regulatory approval for such product candidates;
- be required to amend the protocols for our clinical trials, perform additional nonclinical studies or clinical trials to support approval or be subject to additional post-marketing testing requirements;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings or contraindications; or
- in the event a product candidate is approved, have regulatory authorities withdraw their approval of the product or impose restrictions on its use.

Even if our current and planned clinical trials are successful, we will need to conduct additional clinical trials, which may include registrational trials, trials in additional patient populations or under different treatment conditions, and trials using different manufacturing protocols, processes, materials or facilities or under different manufacturing conditions, before we are able to seek approvals for our product candidates from the FDA and regulatory authorities outside the United States to market and sell these product candidates. If we fail to meet the requirements to support continued clinical development, our clinical development activities for any of our product candidates are delayed or suspended, or we fail to obtain or maintain regulatory approvals with an acceptable scope, our business, prospects, financial condition and results of operations will be harmed.

We are pursuing multiple programs and product candidates in our novel cell therapy development pipeline using an approach that is designed to enable rapid incorporation of new product features. If we elect to incorporate these new features into next-generation product candidates, this may render our existing product candidates obsolete, and we may devote our limited resources in pursuit of a particular program for which there is a greater potential for success and fail to capitalize on development opportunities or product candidates including those which may be more advanced in development.

We focus on the development of programmed cellular immunotherapies for patients with cancer and autoimmune diseases, including off-the-shelf NK- and T-cell product candidates derived from clonal master engineered iPSC lines. Because our iPSC product platform is designed to enable rapid incorporation of novel functional product features in an evolving clinical setting, we may elect to incorporate these discoveries into next-generation product candidates that render our existing product candidates, including product candidates under clinical development, obsolete. Additionally, because we have limited financial and personnel resources, we may elect or be required to abandon or delay the pursuit of opportunities with existing or future product candidates, including those that may be more advanced

in development than those we ultimately elect to pursue. For example, in January 2023, we announced the discontinuation of our FT516, FT596, FT538, and FT536 NK cell programs to focus our resources on advancing our most innovative and differentiated programs. We are also expanding our research and development efforts into areas outside of oncology, such as autoimmune diseases, where we have limited or no experience. Due to these factors, our spending on current and future research and development programs and product candidates and the scientific innovation arising from these expenditures, may not yield commercially viable product candidates.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences following any potential marketing approval.

During the conduct of clinical trials, patients may report changes in their health, including illnesses, injuries and discomforts, to their doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. Regulatory authorities may draw different conclusions and may require us to pause our clinical trials or require additional testing to confirm these determinations, if they occur.

In addition, it is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were not observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, may be reported by subjects or patients. Many times, drug-related side effects are only detectable after investigational products are tested in large-scale pivotal trials or, in some cases, after they are made available to patients on a commercial scale after approval. If additional clinical experience indicates that any of our product candidates have side effects or cause serious or life-threatening side effects, the development of the product candidate may fail or be delayed, or, if the product candidate receives regulatory approval, such approval may be revoked, which would harm our business, financial condition, results of operations and prospects.

Drug-related side effects could also affect subject recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business prospects significantly.

We study our product candidates in patient populations with significant comorbidities that may result in deaths or serious adverse events or unacceptable side effects and require us to abandon or limit our clinical development activities.

Patients treated with our current product candidates may also receive chemotherapy, radiation, and/or other high dose or myeloablative treatments in the course of treatment of their disease, and may therefore experience side effects or adverse events, including death, that are unrelated to our product candidates. While these side effects or adverse events may be unrelated to our product candidates, they may still affect the success of our clinical studies. The inclusion of critically ill patients in our clinical studies may result in deaths or other adverse medical events due to underlying disease or to other therapies or medications that such patients may receive. Any of these events could prevent us from advancing our product candidates through clinical development, and from obtaining regulatory approval, and would impair our ability to commercialize our product candidates. Any inability to advance our existing product candidates or any other product candidate through clinical development would have a material adverse effect on our business, and the value of our common stock would decline.

Because our product candidates are based on novel technologies, it is difficult to predict the regulatory approval process and the time, the cost and our ability to successfully initiate, conduct and complete clinical development, and obtain the necessary regulatory and

reimbursement approvals, required for commercialization of our product candidates. candidates, if approved.

Our cell programming technology and platform for generating cell therapy products using iPSCs represent novel therapeutic approaches, and to our knowledge there are currently no iPSC-derived cell products approved anywhere in the world for commercial sale. As such, it is difficult to accurately predict the type and scope of challenges we may incur during development of our product

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candidates, and we face uncertainties associated with the preclinical and clinical development, manufacture and regulatory requirements for the initiation and conduct of clinical trials, regulatory approval, and reimbursement required for successful commercialization of these product candidates. In addition, because our iPSC-derived cell product candidates are all in the early clinical or preclinical stage, we are currently assessing safety in humans and have not yet been able to assess the long-term effects of treatment. Animal models and assays may not accurately predict the safety and efficacy of our product candidates in our target patient populations, and appropriate models and assays may not exist for demonstrating the safety and purity of our product candidates, as required by the FDA and other regulatory authorities for ongoing clinical development and regulatory approval.

The preclinical and clinical development, manufacture, and regulatory requirements for approval of novel product candidates such as ours can be more expensive and take longer than for other more well-known or extensively studied pharmaceutical or biopharmaceutical product candidates due to a lack of prior experiences on the side of both developers and regulatory agencies. Additionally, due to the uncertainties associated with the preclinical and clinical development, manufacture, and regulatory requirements for approval of our product candidates, we may be required to modify or change our preclinical and clinical development plans or our manufacturing activities and plans, or be required to meet stricter regulatory requirements for approval. Any such modifications or changes could delay or prevent our ability to develop, manufacture, obtain regulatory approval or commercialize our product candidates, which would adversely affect our business, financial condition and results of operations.

Cellular immunotherapies, and iPSC-derived cell therapies in particular, represent relatively new therapeutic areas, and the FDA has cautioned consumers about potential safety risks associated with cell therapies. For example, in November 2023, the FDA announced that it would be conducting an investigation into reports of T-cell malignancies following BCMA-directed or CD19-directed autologous CAR T-cell immunotherapies following reports of T-cell lymphoma in patients receiving these therapies. In January 2024, the FDA determined that new safety information related to T-cell malignancies should be included in the labeling with boxed warning language on these malignancies for all BCMA- and CD19-directed genetically modified autologous T-cell immunotherapies. To date, there are relatively few approved cell therapies, and the development of any cell therapy may be placed on hold by the FDA upon the detection of any unexpected safety event to evaluate the potential relevance of such novel technology to the occurrence of such safety event, highlighting the technical and regulatory risk of working with new technology. As a result, the regulatory approval process for product candidates such as ours is uncertain and may be more expensive and take longer than the approval process for cell therapy product candidates based on other, better known or more extensively studied technologies and therapeutic approaches.

Regulatory requirements in the United States and in other countries governing the development of cell therapy products and therapeutic products created with gene editing technology have changed frequently and the FDA or other regulatory bodies may change the requirements, or identify different regulatory pathways, for approval for any of our product candidates. The FDA previously established the Office of Tissues and Advanced Therapies (OTAT) within the Center for Biologics Evaluation and Research (CBER) to consolidate the review of cell therapy and related products, and to advise CBER on its review. In September 2022, the FDA announced retitling of OTAT to the Office of Therapeutic Products (OTP) and elevation of OTP to a "Super Office" “Super Office" to meet its growing cell and gene therapy workload and new commitments under the Prescription Drug User Fee Act agreement for fiscal years 2023-2027. It is possible that over time new or different divisions may be established or be granted the responsibility for regulating cell and/or gene therapy products, including iPSC-derived cell

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products made with gene editing technology, such as ours. The regulatory review divisions and committees, and any new guidelines they promulgate, may lengthen the regulatory review process, require us to perform additional studies or clinical trials, and delay or prevent development, approval, and commercialization of our product candidates. As a result, we may be required to change our regulatory strategy or to modify our applications for regulatory approval, which could delay and impair our ability to complete the preclinical and clinical development and manufacture of, and obtain regulatory approval for, our product candidates. Changes in regulatory authorities and advisory groups, or any new requirements or guidelines they promulgate, may lengthen the regulatory review process, require us to perform additional studies, increase our development and manufacturing costs, lead to changes in regulatory pathways, positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with the FDA and other

regulatory authorities, and our product candidates will likely be reviewed by an FDA advisory committee. We also must comply with applicable

requirements, and if we fail to do so, we may be required to delay or discontinue development of our product candidates. Delays or unexpected costs in obtaining, or the failure to obtain, the regulatory approval necessary to bring a potential product to market could impair our ability to generate sufficient product revenues to maintain our business.

Preliminary data and interim results we disclose may change as more patient data becomes available or as we make changes to our protocols or manufacturing processes, and such interim results and results from earlier studies may not be predictive of the final results, or of later studies or future clinical trials.

We may from time to time disclose results from preclinical testing or preliminary data or interim results from clinical studies of our product candidates. Such results from preclinical testing, process development and manufacturing activities, and clinical studies,

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including interim clinical trial results as of specified data cutoff dates and results of earlier clinical studies with similar product candidates, are not necessarily predictive of future results, including later clinical trial results.

The results of our current and future clinical trials may differ from results achieved in earlier preclinical and clinical studies for a variety of reasons, including:

- we may not demonstrate the potency and efficacy benefits observed in previous studies;
- our efforts to improve, standardize and automate the manufacture and supply of our product candidates and any resulting deviations in the manufacture of our product candidates, may adversely affect the safety, purity, potency, stability, or efficacy of such product candidates;
- differences in study design, including differences in conditioning regimens, eligibility criteria, and patient populations;
- advancements in the standard of care may affect our ability to demonstrate efficacy or achieve study endpoints in our current or future clinical trials; and
- safety issues or adverse events in patients who enroll in our current or future clinical trials.

Additionally, some clinical trials of our product candidates performed to date were generated from open-label studies and are being conducted at a limited number of clinical sites on a limited number of patients. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which treatment regimen patients have received and may interpret the information of the treated group more favorably given this knowledge. Accordingly, the preliminary data from our Phase 1 clinical trials of certain of our product candidates may not be predictive of future clinical trial results for these or other product candidates when studied in a controlled environment or larger patient populations.

From time to time, we also publish interim, “top-line,” or preliminary data from our clinical studies based on a preliminary analysis of then-available data. Preliminary or interim data from clinical trials that we are conducting are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, the duration of treatment increases and more patient data become available. For example, although we have, from time to time, reported positive interim clinical data for certain of our clinical programs, we may encounter dose-limiting toxicities or unacceptable side effects for these product candidates as dose escalation and expansion progresses in our clinical trials and additional patient data become available. Our preliminary or interim results and related conclusions also are subject to change following a more comprehensive review of the data related to the particular study or trial. Preliminary or “top-line” data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Material adverse changes between preliminary, “top-line,” or interim data and final data could significantly harm our business prospects, financial condition and results of operations.

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Results of clinical testing of any of our existing or future product candidates may fail to show the necessary safety and efficacy required for regulatory approval.

Before obtaining marketing approval from regulatory authorities for the sale of any of our product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy in humans of any such product candidates. 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 outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our product candidates have a limited history of being evaluated in human clinical trials. Any of our product candidates may fail to show the desired safety and efficacy in later stages of clinical development despite having successfully advanced through initial clinical trials.

There is a high failure rate for drugs and biologics proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later stage clinical trials even after achieving promising results in earlier stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit, or prevent regulatory approval. In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development.

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If our product candidates are ultimately not approved for any reason, our business, prospects, results of operations and financial condition would be adversely affected. In addition, the standard of care may change with the approval of new products for the same indications that we are studying.

We are subject to risks associated with the ongoing global COVID-19 pandemic, which could seriously impact the research and development of our product candidates.

The ongoing COVID-19 pandemic has broadly affected the global economy, resulted in significant travel and work restrictions in many regions and put a significant strain on healthcare resources. The pandemic has had, and may continue to have, an impact on our operations and on the operations of our collaborators, third-party contractors and other entities, including governmental agencies with which we interact. For example, in the first two years of the pandemic, state and local regulations required a significant portion of our employees to work remotely, which had an impact on our operations and research and development of our product candidates. We have also experienced delays in obtaining materials and supplies needed to maintain our operations and manufacture our product candidates as a result of production shortages experienced by our suppliers. Additionally, at times we have been subject to temporary pauses in enrollment and dosing implemented by some clinical trial sites due to COVID-19, and some clinical trial sites have also restricted initiation of new trials at times as well as visits by sponsors and clinical research organizations (CROs) for ongoing trials to protect both site staff and patients from possible COVID-19 exposure.

The COVID-19 pandemic, including the emergence of new variants, has impacted, and may in the future impact, the clinical development of our product candidates if we are subject to restrictions or limitations on, or delays in, the performance of study procedures (particularly any procedures that may be deemed non-essential), participant dosing, distribution of our product candidates or clinical trial materials, study monitoring, or site inspections and data analysis, including as a result of changes in hospital or research institution policies, federal, state or local regulations, prioritization of hospital and other medical resources toward pandemic efforts, reduced availability of site staff supporting the conduct of clinical trials, heightened risks of exposure of study participants, principal investigators or site staff to COVID-19 if an outbreak occurs in their geographic region, or other reasons related to the pandemic. Quarantine or other travel limitations (whether voluntary or required) also may impede participant movement, affect access to study sites, or interrupt healthcare services.

Furthermore, the pandemic could cause delays in review and response times by the FDA and other regulatory agencies, or such health regulatory agencies may refuse to accept data from our clinical trials due to mitigation strategies we implement in response to the COVID-19 pandemic or other public health concerns and current regulatory guidance. In addition, our ability to manufacture and ship our product candidates for our clinical trials may be impacted if we, or any third parties which manufacture and supply materials used in either the manufacture of our product candidates or the conduct of our research and development activities, or which perform certain testing relating to our product candidates, are adversely impacted by restrictions resulting from the coronavirus outbreak. There is also the potential that manufacturing facilities, equipment, and materials required for manufacture or administration of our product candidates could be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, which may make it more difficult to obtain materials, equipment, or manufacturing slots necessary for the clinical supply of our product candidates.

The extent to which the pandemic affects our operations and the research and development of our product candidates will depend on continuously changing circumstances, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, including the continued emergence of new variants of the virus, which may impact rates of infection and vaccination efforts and effectiveness, developments or perceptions regarding the safety of vaccines, future waves of infection, and the effectiveness of actions taken to contain the pandemic or mitigate its impact, including vaccination campaigns. While the ultimate

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impact of the COVID-19 pandemic on our business is highly uncertain, any negative impacts that materialize could materially adversely affect our clinical development and operations, financial performance and stock price.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.

Any product candidate for which we obtain marketing approval, along with the manufacturing protocols, processes, materials and facilities, qualification testing, post-approval clinical data, labeling and promotional activities for such product, will be subject to continual and additional requirements of the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information, reports, registration and listing requirements, requirements relating to current cGMP, applicable product tracking and tracing requirements, quality control, quality assurance and corresponding maintenance of records and documents, and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Additionally, under FDORA, the Food and Drug Omnibus Reform Act of 2022 (FDORA), sponsors of approved drugs and biologics must provide 6 months' months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's product's ability to be marketed. The FDA closely regulates the post-approval marketing and promotion of pharmaceutical and biological products to ensure such products are marketed only for the approved indications and in accordance with the provisions of the approved labeling. Later discovery of previously unknown problems with our product candidates, manufacturing operations, or failure to comply with regulatory requirements, may lead to various adverse conditions, including significant delays in bringing our product candidates to market and/or being precluded from manufacturing or selling our product candidates, any of which could significantly harm our business.

We may seek regenerative medicine advanced therapy or RMAT, (RMAT) designation for certain of our product candidates, but such designation may not actually lead to a faster development or regulatory review or approval process and we may be unable to obtain or maintain the benefits associated with such designation.

We may seek regenerative medicine advanced therapy, or RMAT designation from the FDA for certain of our product candidates. A product candidate is eligible for RMAT designation if: (1) it is a cell therapy, therapeutic tissue engineering product, human cell or tissue product, or a combination product using any such therapies or products; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) there is preliminary clinical evidence that indicates that the product candidate has the potential to address unmet medical needs for such disease or condition. This program is intended to facilitate efficient development and expedite review of RMATs. A BLA Biologics License Application (BLA) for a product candidate with RMAT designation may be eligible for priority review or accelerated approval through (1) surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit or (2) reliance upon data obtained from a meaningful number of sites. Benefits of such designation also include early interactions with the FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A product candidate that has RMAT designation and is subsequently granted accelerated approval and is subject to post-approval requirements may fulfill such requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real-world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval. RMAT designation is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for RMAT designation, the FDA may disagree and instead determine not to grant such designation. In any event, the receipt of RMAT designation for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualifies for RMAT designation, the FDA may later decide that the product candidate no longer meets the conditions for qualification.

We may rely on orphan drug status to develop and commercialize certain of our product candidates, but orphan drug designations may not confer marketing exclusivity or other expected commercial benefits and we may not be able to obtain orphan drug designations for our other product candidates.

We may rely on orphan drug exclusivity for product candidates that we may develop. Orphan drug status confers seven years of marketing exclusivity in the United States under the FDCA, Federal Food Drug, and Cosmetic Act, and up to ten years of marketing exclusivity in Europe for a

particular product in a specified indication, subject to certain conditions. However, we may be unable to obtain orphan drug designations for any of our product candidates that we are currently developing or may pursue. Even if we do obtain orphan drug designations and are the first to obtain marketing approval of our product candidates for the applicable indications, we will not be able to rely on these designations to exclude other companies from manufacturing or selling biological products using the same principal molecular structural features for the same indication beyond these timeframes. Furthermore, any marketing

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exclusivity in Europe can be reduced from ten years to six years if the initial designation criteria have significantly changed since the market authorization of the orphan product.

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For any product candidate for which we may be granted orphan drug designation in a particular indication, it is possible that another company also holding orphan drug designation for the same product candidate will receive marketing approval for the same indication before we do. If that were to happen, our applications for that indication may not be approved until the competing company's period of exclusivity expires. Even if we are the first to obtain marketing authorization for an orphan drug indication in the United States, there are circumstances under which a competing product may be approved for the same indication during the seven-year period of marketing exclusivity, such as if the later product is shown to be clinically superior to our orphan product, or if the later product is deemed a different product than ours. Further, the seven-year marketing exclusivity would not prevent competitors from obtaining approval of the same product candidate as ours for indications other than those in which we have been granted orphan drug designation, or for the use of other types of products in the same indications as our orphan product.

We may seek designation for our cell programming technology as a designated platform technology, 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 designation for our cell programming technology as designated platform technology. Under FDORA, a platform technology incorporated within or utilized by a drug or biological product is eligible for designation as a designated platform technology if (1) the platform technology is incorporated in, or utilized by, a drug approved under a BLA or NDA; (2) preliminary evidence submitted by the sponsor of the approved or licensed drug, or a sponsor that has been granted a right of reference to data submitted in the application for such drug, demonstrates that the platform technology has the potential to be incorporated in, or utilized by, more than one drug without an adverse effect on quality, manufacturing, or safety; and (3) data or information submitted by the applicable person indicates that incorporation or utilization of the platform technology has a reasonable likelihood to bring significant efficiencies to the drug development or manufacturing process and to the review process. A sponsor may request the FDA to designate a platform technology as a designated platform technology concurrently with, or at any time after, submission of an IND application for a drug that incorporates or utilizes the platform technology that is the subject of the request. If so designated, the FDA may expedite the development and review of any subsequent original BLA or NDA for a drug that uses or incorporates the platform technology. Even if we believe our cell programming technology meets the criteria for such designation, the FDA may disagree and instead determine not to grant such designation. In addition, the receipt of such designation for a platform technology does not ensure that a drug will be developed more quickly or lead to a faster FDA review or approval process and does not assure ultimate FDA approval of a drug. Moreover, the FDA may revoke a designation if the FDA determines that a designated platform technology no longer meets the criteria for such designation.

We may seek approval of our product candidate into RTOR. This program may not lead to a faster regulatory review or approval process and does not increase the likelihood that our product candidate(s) will receive marketing approval.

Participation in RTOR is voluntary. Our acceptance into RTOR does not guarantee or influence approval of our application, which is subject to the same statutory and regulatory requirements for approval as applications that are not included in RTOR. Although early approvals have occurred with applications selected for RTOR, this may not be the case for our application even if it is selected for RTOR. If at any time the FDA determines our participation in RTOR, if selected, is no longer appropriate, the FDA may rescind our acceptance and instruct us to follow routine submission procedures for marketing approval.

We may be subject to certain regulations, including federal and state healthcare fraud and abuse laws, physician payment transparency laws, anti-bribery and anti-corruption laws and health information privacy and security laws. Any actual or perceived failure to comply with

these regulations could have a material adverse effect on our business and financial condition.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be subject to various federal and state healthcare laws, including, without limitation, fraud and abuse laws, false claims laws, data privacy and security laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers. These laws may impact, among other things, our proposed sales, marketing and education programs. Additionally, we may be subject to state and foreign equivalents of such healthcare laws and regulations, some of which may be broader in scope and may apply regardless of the payor, as well as patient privacy regulation by both the federal government and the states in which we conduct our business. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge and may not comply under one or more of such laws, regulations, and guidance. Law enforcement authorities are increasingly focused on enforcing fraud and abuse laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our current and future business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. If our operations, including our arrangements with physicians and other healthcare providers are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including,

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without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs (such as Medicare and Medicaid), and imprisonment, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our financial results. For more information regarding the risks related to such laws and regulations please see "*Business – Government Regulation – Other Healthcare Laws and Compliance Requirements.*"

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations.

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The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of European Union Member States, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and individual 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 individual imprisonment.

A variety of risks associated with conducting research and clinical trials abroad and marketing our product candidates internationally could materially adversely affect our business.

We plan to develop and potentially commercialize our product candidates worldwide. Accordingly, we expect that we will be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- increased difficulties in managing the logistics and transportation of storing and shipping product candidates produced in the U.S. and shipping the product candidate to the patient abroad;

the product candidate to the patient abroad;

- import and export requirements and restrictions;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with data privacy regulations in foreign countries;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems, and price controls;
- potential liability under the U.S. Foreign Corrupt Practices Act or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

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- business interruptions resulting from geo-political actions, including war and terrorism, such as the ongoing wars between Russia and Ukraine and between Israel and Hamas.

These and other risks associated with our potential international operations may materially adversely affect our ability to attain or maintain profitable operations, which could have a material adverse effect on our business and results of operations.

We may decide to conduct clinical trials for our product candidates outside the United States, and the FDA may not accept data from trials conducted in such locations.

To date, we have only conducted clinical trials in the United States. However, we may in the future choose to conduct one or more of our clinical trials or include sites in current or future clinical trials outside the United States.

Although the FDA may accept data from sites or clinical trials outside the United States, acceptance of these data is subject to conditions imposed by the FDA. The FDA will generally not consider the data from a foreign clinical trial not conducted under an IND unless (i) the trial was well-designed and well-conducted in accordance with Good Clinical Practice (GCP) requirements, including requirements for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials in a way that provides assurance that the data and reported results are credible and accurate and that the rights, safety, and well-being of trial subjects are protected, and (ii) the FDA is able to validate the data from the trial through an onsite inspection, if necessary. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such as inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering must be met. Many foreign regulatory authorities have similar approval requirements. In addition, while these clinical trials or trial sites are subject to the applicable local laws where the trials are conducted, FDA acceptance of the data will depend on its determination that the trials or trial sites also complied with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside the United States. If the FDA does not accept the data from any trial or trial site outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and would delay or halt our development of the applicable product candidates.

Risks Related to Our Reliance on Third Parties

We are, and expect to continue to be, dependent on third parties to conduct some or all aspects of manufacturing of our product candidates for use in clinical trials and for commercial sale, if approved. Our business could be harmed if those third parties fail to perform satisfactorily.

While we currently manufacture clinical supplies of our iPSC-derived cell product candidates at our cGMP facilities located in San Diego,

California, we also rely on third parties to manufacture certain components required for the manufacture of our product candidates, and we may rely on third parties to conduct some or all aspects of manufacturing of our product candidates for use in conducting later stage clinical trials and for commercial sale upon approval of any of our product candidates.

Reliance on third parties for manufacture of our product candidates and components utilized in manufacturing our product candidates entails certain risks, including reliance on the third party for regulatory compliance and quality assurance, the possibility that the third-party manufacturer does not maintain the financial, personnel or other resources to meet its obligations, the possibility that the third party fails to manufacture such components, or our product candidates or any products we may eventually commercialize, in accordance with our specifications, misappropriation of our proprietary information, including our trade secrets and know-how, and the possibility of termination of our manufacturing relationship by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP, cGTP and similar jurisdictional standards. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The FDA or similar foreign regulatory agencies may also implement new standards at any time, or change their interpretations and enforcement of existing standards for manufacture, packaging or testing of products. We have little control over our manufacturers' compliance with these regulations and standards.

In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to a particular CMO, and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier if needed, or we may be unable to transfer such skills at all. In addition, if we are required to change contract manufacturers for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to

the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies produced by different manufacturers, which could require the conduct of additional clinical trials.

Further, we depend in some instances on third party suppliers, including sole source suppliers, for the provision of reagents, materials, devices and equipment that are used by us and our third-party contract manufacturers in the production of our product candidates, including certain of our iPSC-derived cell therapy product candidates. Any disruption to or loss of supply from any of these suppliers could delay our clinical development and commercialization efforts, which would adversely affect our business, prospects, results of operations and financial condition.

The termination of our collaboration with Janssen will have a material impact on our business and could result in disruptions to our operations that have a material adverse effect on our business and financial condition.

The termination of our Collaboration and Option Agreement with Janssen is expected to take effect on April 3, 2023. As a result of this termination, we have discontinued development of two collaboration candidates that were expected to enter clinical development in 2023. We have also prioritized our pipeline and substantially reduced our operating costs, including by implementing

a company-wide reduction in force, to fund our operations into the second half of 2025. For more information on the termination of our collaboration with Janssen, see the section titled, "*Business - Discontinued Product Candidates*". For more information on the risks associated with our reduction in force, see *"- Risks Related to Our Business and Industry"*.

We depend on strategic partnerships and collaboration arrangements for the development and commercialization of certain of our product candidates in certain indications or geographic territories, and if these arrangements are terminated or are unsuccessful, this could result in delays and other obstacles in the development, manufacture or commercialization of any of our product candidates and materially harm our results of operations

results of operations.

Our strategy for fully developing and commercializing our product candidates is dependent upon maintaining our current arrangements and establishing new arrangements with research collaborators, corporate collaborators and other third parties. We currently have a corporate collaboration agreement with Ono; our collaboration with Janssen will terminate terminated effective April 2023. Our collaboration agreement with Ono provides for, among other things, research funding and significant future payments should certain development, regulatory and commercial milestones be achieved. Under our arrangement with Ono and any future corporate arrangements that we may form, our corporate collaborators may be responsible for:

- electing to advance product candidates through preclinical and into clinical development;
- conducting clinical development and obtaining required regulatory approvals for product candidates; and
- commercializing any resulting products.

As a result, we may not be able to conduct such corporate collaborations in the manner or on the time schedule we currently contemplate, which may negatively impact our business operations.

Our lack of control over the research funding for, and the development and commercialization of, certain of our product candidates being developed under the Ono Agreement and any other product candidates that we may develop under a future arrangement could cause delays or other difficulties in the development and commercialization of any of our product candidates, which may prevent completion of research and development activities and intended regulatory filings in a timely fashion, if at all. Because we expect to continue to rely on our current collaborator and to enter into new collaborations in the future, the development and commercialization of any of our product candidates could be substantially delayed, and our ability to receive future funding could be substantially impaired, if one or more of our current or future collaborators:

- shifts its priorities and resources away from our collaborations due to a change in business strategies, or a merger, acquisition, sale or downsizing of its company or business unit;
- ceases development in therapeutic areas which are the subject of our collaboration;
- fails to select a product candidate for advancement into preclinical development, clinical development, or subsequent clinical development into a marketed product;
- changes the success criteria for a particular product candidate, thereby delaying or ceasing development of such product candidate;
- significantly delays the initiation or conduct of certain activities which could delay our receipt of milestone payments tied to such activities, thereby impacting our ability to fund our own activities;
- develops a product candidate that competes, either directly or indirectly, with our product candidates;
- does not obtain the requisite regulatory approval of a product candidate;
- does not successfully commercialize a product candidate;
- encounters regulatory, resource or quality issues and be unable to meet demand requirements;

- exercises its rights under the agreement to terminate the collaboration, as Janssen did in January 2023, or otherwise withdraws support for, or otherwise impairs development under the collaboration;
- disagrees on the research, development or commercialization of a product candidate resulting in a delay in milestones, royalty payments or termination of such product candidate; and
- uses our proprietary information or intellectual property in such a way as to jeopardize our rights in such property.

In addition, the termination of the Ono Agreement or any future strategic partnership or collaboration arrangement that we enter into may prevent us from receiving any milestone, royalty payment, sharing of profits, and other benefits under such agreement. Furthermore, disagreements with these parties could require or result in litigation or arbitration, which would be time-consuming and

expensive. Any of these events could have a material adverse effect on our ability to develop and commercialize any of our product candidates and may adversely impact our business, prospects, financial condition, and results of operations.

Cell-based therapies depend on the availability of reagents and specialized materials and equipment which in each case are required to be acceptable to the FDA and foreign regulatory agencies, and such reagents, materials, and equipment may not be available to us on

acceptable to the FDA and foreign regulatory agencies, and such reagents, materials, and equipment may not be available to us on

acceptable terms or at all. We rely on third-party suppliers for various components, materials and equipment required for the conduct of our clinical trials and the manufacture of our product candidates and do not have supply arrangements for certain of these components.

The development and manufacturing of our product candidates requires many reagents and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. To date, we and our CMOs have purchased equipment, materials and disposables used for the manufacture of our existing product candidates from third-party suppliers. Some of these suppliers may not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. Reagents and other key materials from these suppliers may have inconsistent attributes and introduce variability into our manufactured product candidates, which may contribute to variable patient outcomes and possible adverse events. We rely on the general commercial availability of materials and equipment required for the manufacture of our product candidates, and do not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Even if we are able to enter into such contracts, we may be limited to a sole third-party for the supply of certain required components and equipment.

In addition, the clinical development of our product candidates depends on the availability of certain materials and agents used in our clinical trials. For example, certain of our clinical trial protocols require the use of cyclophosphamide and fludarabine, agents which are routinely used in oncology studies, and which we use in our clinical trial protocols to condition patients for treatment with our product candidates. Further, we intend to develop certain of our product candidates as a combination therapy with other cancer therapies, such as monoclonal antibodies, requiring availability and use of these monoclonal antibodies in certain of our clinical trial protocols. Recently, the FDA has reported a shortage of fludarabine, and some clinical trial sites may in the future institute enrollment holds or halt enrollment of patients if sufficient quantities of fludarabine cannot be secured. We cannot predict the extent and duration of this shortage of fludarabine, although any Any failure or delays by us or by our clinical sites to obtain sufficient quantities of fludarabine, monoclonal antibodies materials and agents required under our protocols, or other components and agents necessary for the conduct of our clinical trials, may delay our ability to enroll and treat patients in, or complete, our current or future clinical trials of our product candidates on time, if at all.

As a result of the ongoing COVID-19 pandemic or other any public health crises, the business and operations of our suppliers and other third parties which produce agents and materials used in our clinical trials or manufacturing of our product candidates may be disrupted or delayed, and we in turn may experience disruptions or delays in our supply chain. A delay or inability to continue to source product or materials from any of these suppliers or third parties, which could be due to the impacts of any public health crises, natural disasters (including due to the COVID-19 pandemic or other pandemics, effects of climate change), ongoing wars, including the ongoing conflict in wars between Russia and Ukraine and between Israel and Hamas, regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, or quality issues, could adversely affect our ability to manufacture our product candidates and our ability to conduct clinical trials, which could significantly harm our business.

If we are required to change suppliers, or modify the components, equipment, materials or disposables used for the manufacture of our product candidates, we may be required to change our manufacturing operations or clinical trial protocols or to provide additional data to regulatory authorities in order to use any alternative components, equipment, materials or disposables, any of which could set back, delay, or increase the costs required to complete our clinical development and commercialization of our product candidates. Additionally, any such change or modification may adversely affect the safety, efficacy, stability, or potency of our product candidates, and could adversely affect our clinical development of our product candidates and harm our business.

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We currently rely on third parties to conduct certain research and development activities and clinical trials of our product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to timely develop, manufacture, obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We rely upon third parties, including medical institutions, clinical investigators, and CROs clinical research organizations (CROs) for the conduct of certain research and preclinical development activities, process development and manufacturing activities, and for the conduct, management, and supervision of clinical trials of our product candidates. We do not have direct control over the activities of these third parties, and may have limited influence over their actual performance. Our reliance on these third parties and CROs does not relieve us of our responsibilities to ensure that our clinical studies are conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards.

We are responsible for complying, and we are responsible for ensuring that our third-party service providers and CROs comply, with applicable GCP for conducting activities for all of our product candidates in clinical development, including conducting our clinical trials, and recording and reporting data from these trials. Regulatory authorities enforce these regulations through periodic inspections of trial sponsors, principal investigators and trial sites. We cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with applicable GCP requirements. In addition, our registrational clinical trials must be conducted with product produced under applicable regulatory requirements.

If these third parties and CROs do not successfully carry out their contractual duties or obligations, meet expected deadlines or successfully complete activities as planned, or if the quality or accuracy of the research, preclinical development, process development, manufacturing, or clinical data they obtain is compromised due to the failure to adhere to applicable regulatory and manufacturing requirements or for other reasons, our research, preclinical development, process development and manufacturing activities, and clinical trials, and the development of our product candidates, may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Further, if our agreements with third parties or CROs are terminated for any reason, the development of our product candidates may be delayed or impaired, and we may be unable to advance our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed or impaired.

If conflicts arise between us and our collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.

If conflicts arise between our corporate or academic collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Some of our academic collaborators and strategic partners are conducting multiple product development efforts within each area that is the subject of the collaboration with us. Our collaborators or strategic partners, however, may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of our collaborators' collaborators' or partners' partners' support for our product candidates.

Some of our collaborators or strategic partners could also become our competitors in the future. Our collaborators or strategic partners could develop competing products, preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely, or fail to devote sufficient resources to the development and commercialization of our product candidates. Any of these developments could harm our product development efforts.

Risks Related to Our Intellectual Property

If we are unable to protect our intellectual property, or obtain and maintain patent protection for our technology and product candidates, other companies could develop products based on our discoveries, which may reduce demand for our products and harm our business.

Our commercial success will depend in part on our ability to obtain and maintain intellectual property protection for our product candidates, the operations used to manufacture them and the methods for using them, and also for our cell programming technology in order to prevent third parties from making, using, selling, offering to sell or importing our product candidates or otherwise exploiting our cell programming approach. The scope of patent protection in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. One aspect of the determination of patentability of our inventions depends on the scope and content of the “prior art,” information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual

property upon our freedom to operate, is highly uncertain. Because patent applications in the United States and most other countries are confidential for typically a period of 18 months after filing, or may not be published at all, we cannot be certain that we were the first to file any patent application related to our product candidates. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are uncertain. We own and have exclusive licenses to patent portfolios for our product candidates and cell programming technology, although we cannot be certain that our existing

have exclusive licenses to patent portfolios for our product candidates and cell programming technology, although we cannot be certain that our existing patents and patent applications provide adequate protection or that any additional patents will issue to us with claims that provide adequate protection of our other product candidates. Further, we cannot predict the breadth of claims that may be enforced in our patents if we attempt to enforce them or if they are challenged in court or in other proceedings. If we are unable to secure and maintain protection for our product candidates and cell programming technology, or if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

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Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference, opposition, reexamination, review, reissue, post grant review or invalidity proceedings before U.S. or non-U.S. patent offices. The scope, validity or enforceability of our patents or the patents of our licensors may be challenged in such proceedings in either the courts or patent offices in the United States and abroad, and our business may be harmed if the coverage of our patents or the patents of our licensors is narrowed, or if a patent of ours or our licensors is judged invalid or unenforceable, in any such proceedings.

Furthermore, our intellectual property rights may be subject to a reservation of rights by one or more third parties. For example, the research resulting in certain of the patent rights and technology that we own or have licensed was funded in part by the U.S. government. As a result, the government has certain rights, including march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention or to have others use the invention on its behalf. These rights may permit the government to disclose our information to third parties and to exercise march-in rights to use or allow third parties to use our technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights or by any third party of its reserved rights could harm our competitive position, business, financial condition, results of operations, and prospects.

We depend on our licensors to prosecute and maintain patents and patent applications that are material to our business. Any failure by our licensors to effectively protect these intellectual property rights could adversely affect our business and operations.

Certain rights to our key technologies and product candidates, including intellectual property relating to our iPSC technology, are licensed from third parties. As a licensee of third-party intellectual property, we rely on our licensors to file and prosecute patent applications and maintain patents, and otherwise protect the licensed intellectual property under some of our license agreements. We have not had and do not have primary control over these activities for certain of our licensed patents, patent applications and other intellectual property rights, and we cannot be certain that such activities will result in valid and enforceable patents and other intellectual property rights. Additionally, our licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and we cannot be certain that our licensors will allocate sufficient resources or prioritize enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business.

If we fail to comply with our obligations under our license agreements, we could lose rights to our product candidates or key technologies.

We have obtained rights to develop, market and sell some of our product candidates through intellectual property license agreements with third parties. These license agreements impose various diligence, milestone payment, royalty and other obligations on us. In particular, under our Amended and Restated Exclusive License Agreement dated May 15, 2018 (the Amended MSK (Amended MSKCC License) with Memorial Sloan Kettering Cancer Center (MSK), MSKCC, in the event a licensed product achieves a specified clinical milestone, MSK MSKCC is eligible to receive from us certain milestone payments totaling up to $75.0 million based on the price of our common stock, where the amount of such payments owed to MSK MSKCC is contingent upon certain increases in the price of our common stock following the date of achievement of such clinical milestone. If we fail to comply with our obligations under our license agreements, including any payment obligations, we could lose some or all of our rights to develop, market and sell products covered by these licenses, and our ability to form collaborations or

partnerships may be impaired. In addition, disputes may arise under our license agreements with third parties, which could prevent or impair our ability to maintain our current licensing arrangements on acceptable terms and to develop and commercialize the affected product candidates.

We are and may be become involved in litigation or other proceedings from time to time relating to the enforcement or defense of patent and other intellectual property rights, which could cause us to divert our resources and could put our intellectual property at risk.

To prevent infringement or unauthorized use of our intellectual property, we have in the past, and may in the future, need to file infringement claims. For example, in May 2022, we filed a patent infringement lawsuit in the Southern District of California against Shoreline Biosciences, Inc. and Dr. Dan Kaufman. Refer to (see *"Item 3. Legal Proceedings in this Annual Report on Form 10-K Proceedings"* for a more detailed description of this matter. matter). When we pursue litigation to stop another party from using the inventions claimed in any patents we own or control, that party has the right to ask the court to rule that such patents are invalid or should not be enforced against that third party. In addition to patent infringement lawsuits, we may decide to file interferences, oppositions, *ex parte* reexaminations, post-grant review, or *inter partes* review proceedings before the U.S. Patent and Trademark Office (the USPTO) and corresponding foreign patent offices. Litigation and other proceedings relating to intellectual property are unpredictable and expensive and may consume time and resources and divert the attention of managerial and scientific personnel. Such litigations and proceedings could substantially increase our operating losses and reduce the resources available for research, development, and other activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings or may be required to divert such resources from our ongoing and planned research and development activities. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing or misappropriating or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

There also is a risk that a court or patent office in such proceeding will decide that our patents or the patents of our licensors are not valid or are not enforceable, and that we do not have the right to stop the other party from using the inventions. Additionally, even if the validity of such patents is upheld, the court may refuse to stop the other party on the ground that such other party's activities do not infringe our rights to such patents. If we are not successful in enforcing or defending our intellectual property, our competitors could develop and market products based on our discoveries and technologies, which may reduce the commercial viability of, and demand for, our product candidates and any future products.

We or our strategic partners may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing, or increase the costs of commercializing, our product candidates.

Our success will depend, in part, on our ability to operate without infringing the proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, *ex parte* reexaminations, post-grant review, and *inter partes* review proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights or misappropriation of other intellectual property rights of third parties.

We cannot be certain that any of our 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 every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or intellectual property rights 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 incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

We cannot guarantee that the manufacture, use or marketing of our existing product candidates or any other product candidates that we develop, or the use of our cell programming technology, will not infringe third-party patents. There may be third-party patents or patent applications with claims to materials, cell compositions, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Our competitors may have filed, and may in the future file, patent applications covering

products and technologies similar to ours. Because patent applications can take many years to issue, there may be currently pending patent applications which may 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.

Third parties asserting their patent or other intellectual property rights 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 or force us to cease some of our business operations. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, cause development delays, and may impact our reputation. 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, obtain one or more licenses from third parties, pay royalties, or redesign our infringing products, which may be impossible on a cost-effective basis or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for development or manufacture of our product candidates which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

We own or license from third parties certain intellectual property rights necessary to develop and manufacture our product candidates. The growth of our business will likely depend in part on our ability to acquire or in-license additional proprietary rights, including to advance our research or allow commercialization of our product candidates. In that event, we may be required to expend considerable time and resources to develop or license replacement technology. For example, our programs may involve additional technologies or product candidates that may require the use of additional proprietary rights held by third parties. Furthermore, other pharmaceutical or biotechnology companies and academic institutions may also have filed or are planning to file patent applications

potentially relevant to our business. From time to time, in order to avoid infringing these third-party patents, we may be required to license technology from additional third parties to further develop or commercialize our product candidates. We may be unable to acquire or in-license any relevant third-party intellectual property rights, including any such intellectual property rights required to manufacture, use or sell our product candidates, that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, and as a result we may be unable to develop or commercialize the affected product candidates, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches or technology that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license under such intellectual property rights, any such license may be non-exclusive, which may allow our competitors' access to the same technologies licensed to us.

Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. In addition, it may be more costly for us to secure and maintain the necessary patent protection to block third parties from using our technology than to negotiate out-licenses or similar agreements with these parties to provide them with limited rights to use our technology. There can be no assurance that we will be able to successfully complete any such negotiations and ultimately acquire or maintain, on commercially viable terms, the rights to the intellectual property required for the successful development and commercialization of our product candidates.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

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:

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- others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries;

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- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents are valid, enforceable and infringed;
- we may from time to time initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- 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 such intellectual property;
- we may fail to adequately protect and police our trademarks and trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed alleged trade secrets.

In conducting our business operations, we have obtained confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors 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 our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or other parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we could lose valuable intellectual property rights or personnel, which could adversely affect 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 may be subject to claims challenging the inventorship 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. If we fail in defending any such claims, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. We may also be subject to monetary damages, and any of these outcomes could have a material adverse impact on our business.

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Proprietary information and invention assignment agreements with our employees and third parties may not prevent unauthorized disclosure of our trade secrets and other proprietary information.

In addition to the protection afforded by patents, we also rely upon unpatented trade secrets and improvements, proprietary know-how, and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, through confidentiality agreements with our collaborators, employees and consultants. We also have invention or patent assignment agreements with our employees and some, but not all, of our collaborators and consultants. Because we expect to rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Trade secrets, however, may be difficult to protect, and any disclosure, either intentional or unintentional, by our employees or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Although we use reasonable efforts to protect our trade secrets, our employees or former employees, consultants, outside scientific advisors, contractors, and collaborators might intentionally or inadvertently disclose our trade secret information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Despite these efforts, 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. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them from using that technology or information to compete with us. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in

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protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, or misappropriation of our intellectual property by third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results, and financial condition.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our 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. 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 may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with any products that we may develop and commercialize, 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 in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, 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 and 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. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Changes in the patent law in the United States could diminish the value of patents in general, thereby impairing our ability to protect our product candidates and technology.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property rights, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and is therefore obtaining and enforcing biotechnology patents is costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. 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. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has

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created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

The term of our patents may not be sufficient to effectively protect our market position and products.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Even if we obtain patents covering our product candidates, once the patent life has expired for a product, we may be open to competition from other products. If the lives of our patents are not sufficient to effectively protect our products and business, our business and results of operations will be adversely affected.

Risks Related to the Commercialization of Our Product Candidates

We do not have experience marketing any product candidates and do not have a sales force or distribution capabilities, and if our products are approved, we may be unable to commercialize them successfully.

We currently have no experience in marketing and selling therapeutic products, including obtaining and maintaining adequate pricing and reimbursements. If any of our product candidates are approved for marketing, we intend to establish marketing and sales capabilities internally or we may selectively seek to enter into partnerships with other entities to utilize their marketing and distribution capabilities. If we are unable to develop adequate marketing and sales capabilities on our own or effectively partner with third parties, our ability to generate product revenues will suffer.

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The commercial success of our product candidates will depend upon the degree of market acceptance by physicians, patients, third-party payers and others in the medical community.

The commercial success of our products, if approved for marketing, will depend in part on the medical community, patients and third-party payers accepting our product candidates as effective and safe. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. For example, in November 2023, the FDA announced that it would be conducting an investigation into reports of T-cell malignancies following BCMA-directed or CD19-directed autologous CAR T-cell immunotherapies following reports of T-cell lymphoma in patients receiving these therapies. In January 2024, the FDA determined that new safety information related to T-cell malignancies should be included in the labeling with boxed warning language on these malignancies for all BCMA- and CD19-directed genetically modified autologous T-cell immunotherapies. FDA's investigation into CAR T-cell therapies and other similar actions could result in increased government regulation, unfavorable public perception and publicity, stricter labeling requirements for those product candidates that are approved, and a decrease in demand for any such product candidates. The degree of market acceptance of our products, if approved for marketing, will depend on a number of factors, including:

- the safety and efficacy of the products, and advantages over alternative treatments;
- the labeling of any approved product;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- the clinical indications for which any product candidate is approved;
- the emergence, and timing of market introduction, of competitive products;
- the effectiveness of our marketing strategy;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- obtaining and maintaining adequate pricing and reimbursement; and
- sufficient third-party insurance coverage or governmental reimbursement, which may depend on our ability to provide compelling evidence that a product meaningfully improves health outcomes to support such insurance coverage or reimbursement.

The patient populations targeted by our autoimmune product candidates are also typically not at risk of near-term death, even if they may suffer life-threatening symptoms, so those patients will need to deem the benefits of cell therapy to be worth the risk of unknown potential adverse side effects. Our success in this space will depend upon physicians who specialize in the treatment of

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autoimmune diseases targeted by our product candidates prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are more familiar and for which greater clinical data may be available.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be known until after it is launched. Any failure to achieve market acceptance for our product candidates will harm our business, results and financial condition.

We expect to face uncertainty regarding the pricing of our existing product candidates and any other product candidates that we may develop. If pricing policies for our product candidates are unfavorable, our commercial success will be impaired.

Due to the novel nature of our cellular immunotherapy product candidates, we face significant uncertainty as to the pricing of any such products for which we may receive marketing approval. While we anticipate that pricing for any cellular immunotherapy product candidates that we develop will be relatively high due to their anticipated use in the prevention or treatment of life-threatening diseases where therapeutic options are limited, the biopharmaceutical industry has recently experienced significant pricing pressures. In particular, drug pricing and other healthcare costs continue to be subject to intense political and societal pressures, which we anticipate will continue and escalate on a global basis. These pressures may result in harm to our business and reputation, cause our stock price to decline or experience periods of volatility and adversely affect results of operations and our ability to raise funds.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates could limit our product revenues.

Our ability to commercialize any of our product candidates successfully will depend in part on the availability of coverage and reimbursement for these products from third-party payors, including government health administration authorities, private health insurers, and other managed care organizations. The availability and extent of reimbursement by governmental and private payors is essential for most patients who generally rely on third-party payors to reimburse all or part of the costs of their care, including treatments such as cellular immunotherapy. Because our product candidates represent new approaches to the treatment of cancer, there is significant uncertainty as to the insurance coverage and reimbursement status of any product candidates for which we may receive regulatory approval. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services (CMS), an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare, and private payors tend to follow CMS determinations to a substantial degree. If reimbursement or insurance coverage is not available for our product candidates, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be sufficient to allow us to establish or maintain pricing to generate income. Factors payors consider in determining reimbursement are based on whether the product is: (i) a covered benefit under its health plan; (ii) safe, effective and medically necessary; (iii) appropriate for the specific patient; (iv) cost-effective; and (v) neither experimental nor investigational. For more information regarding the risks related to insurance coverage and reimbursement, please see "*Business - Government Regulation - Coverage and Reimbursement.*"

In addition, reimbursement agencies in foreign jurisdictions may be more conservative than those in the United States. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits. Moreover, increasing efforts by

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governmental and third-party payors, in the United States and abroad, 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. Failure to obtain or maintain adequate reimbursement for any products for which we receive marketing approval will adversely affect our ability to achieve commercial success, and could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

If the market opportunities for our product candidates are restricted or smaller than we believe they are, our revenues may be adversely affected and our business may suffer. Because the target patient populations of our product candidates are may be small and variable, we must be able to successfully identify patients and capture a significant market share to achieve and maintain profitability.

We focus our research and development on product candidates for rare diseases, including cancer and autoimmune disorders. diseases. The FDA often approves new therapies initially only for use in patients with relapsed or refractory advanced disease. We expect to initially seek approval of our product candidates in this setting. these settings. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval in earlier lines of treatment. There is no guarantee that our product candidates, even if approved, would be approved for earlier lines of therapy, and, prior to any such approvals, we will have to conduct additional clinical trials, including potentially comparative trials against approved therapies. Certain of our product candidates also target similar patient populations as autologous cell therapy product candidates, including approved autologous CAR T products. Our therapies may not be as safe and

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effective as approved autologous CAR T therapies and as a result, such product candidates may only be approved for patients who are ineligible for autologous CAR T therapy.

Our projections of the number of people who have or will have the diseases we may be targeting, as well as the subset of patients with these cancers in a position to receive second or later lines of therapy and who have the potential to benefit from treatment with our product candidates, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients in the United States, Europe and elsewhere may turn out to be lower than expected, or the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates, all of which would adversely affect our results of operations and our business. Additionally, because our target patient populations are may be small and variable, we may never achieve profitability without capturing a significant market share or obtaining regulatory approval for additional indications for our products.

We may be subject to healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits and future earnings.

Although we do not currently have any products on the market, if we obtain FDA approval for any of our product candidates and begins commercializing our products, we may be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers, physicians, third-party payors, and others play a primary role in the recommendation and prescription of our product candidates, if approved. Our future arrangements with third-party payors will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute our product candidates, if we obtain marketing approval. For more information regarding the risks related to such laws and regulations please see "Business - Government Regulation - Other Healthcare Laws and Compliance Requirements."

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. Even if precautions are taken, it is possible that governmental authorities will conclude that our business practices could, despite efforts to comply, be subject to challenge under current or

possible that governmental authorities will conclude that our business practices could, despite efforts to comply, be subject to challenge under current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect our business in an adverse way.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with

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different compliance or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Healthcare legislative or regulatory reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Payors, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. Additional changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under the health insurance exchanges and fraud and abuse and enforcement. Continued implementation of the ACA Affordable Care Act (ACA) and the passage of additional laws and regulations may result in the expansion of new programs such as Medicare payment for performance initiatives, and may impact existing government healthcare programs, such as by improving the physician quality reporting system and feedback program. For more information regarding the risks related to such recently enacted and future legislation please see *"Business – Government Regulation – Healthcare Reform and Other Regulatory Changes."*

There has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs.

The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any of our product candidates, if approved;
- the ability to set a price that we believe is fair for any of our product candidates, if approved;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare drugs and services, which could result in reduced demand for our drug 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 drug access and marketing cost disclosure and transparency measures, and 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, financial condition, results of operations 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. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

Risks Related to Our Business and Industry

The success of our existing product candidates is substantially dependent on developments within the field of cellular immunotherapy, and specifically developments relating to the use of pluripotent or genome edited cells for the manufacture of cellular therapeutics, some the majority of which are beyond our control.

Our product candidates are designed and are being developed as therapeutic entities for use as cellular immunotherapies, and all of our current product candidates are based on our novel iPSC product platform. Additionally, some of our product candidates utilize novel genome editing technologies. To date, there is limited clinical trial experience testing iPSC-derived therapeutic product candidates and using genome edited therapeutics. cells. The fields of cellular and genome edited therapies are evolving, and as more therapeutic product candidates derived from pluripotent and genome edited cells are reviewed by regulatory authorities, regulatory authorities may impose additional requirements for approval that were not previously anticipated. There have also been several significant adverse events from gene therapy treatments in the past, including reported cases of leukemia and death. Additionally, in November 2023, the FDA announced that it would be conducting an investigation into reports of T-cell malignancies following BCMA-directed or CD19-directed autologous CAR T-cell immunotherapies following reports of T-cell lymphoma in patients receiving these therapies. In January 2024, the FDA determined that new safety information related to T-cell malignancies should be included in the labeling with boxed warning language on these malignancies for all BCMA- and CD19-directed genetically modified autologous T-cell immunotherapies. There can be no assurance that any product candidates developed from or related to our iPSC product platform or any of our research programs will not cause severe or undesirable side effects or result in significant delays or unanticipated costs, or that such development problems can be solved. Any adverse developments in the fields of cellular immunotherapy or genome edited therapy, will such as FDA's investigation into CAR T-cell therapies and other similar actions could negatively affect our ability to develop and commercialize our product candidates.

We face intense competition in an environment of rapid technological and scientific progress from other biotechnology and pharmaceutical companies that are commercializing, have developed or may develop product candidates for the treatment of the diseases that we may target, including companies developing novel therapies and platform technologies. If these companies develop product candidates or platform technologies more rapidly than we do, if their commercialized products or product candidates are more effective, more cost effective, or have fewer side effects, or if they compete in various other aspects of our business, our ability to develop and successfully commercialize product candidates and to execute on our business plans will be adversely affected.

The biotechnology and pharmaceutical industries are intensely competitive and characterized by rapid and significant innovation, particularly in the areas of immune-oncology and the development and commercialization of cell therapies. We compete with a variety of large pharmaceutical companies, multinational biopharmaceutical companies, other biopharmaceutical companies and specialized biotechnology companies, as well as technology and/or therapeutics being developed at universities and other research

institutions. Many of our competitors have greater financial and other resources, such as larger research and development staff, more experienced manufacturing organizations and facilities and greater sales and marketing organizations. Third parties are commercializing, have developed, are developing or may develop product candidates, platform technologies and processes that compete with ours. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community, as well as novel treatments that are currently in preclinical or clinical development or may otherwise enter the market. We believe that a significant number of product candidates are currently under development, including various cellular immunotherapies as well as multifunctional targeted antibodies, such as bi-specific and tri-specific T-cell engagers, which may become commercially available in the future for the treatment of indications, including a variety of cancers, for which we are developing or may try to develop our product candidates. Should one or more of these competing product candidates or other competing product candidates of which we are not aware receive regulatory approval or otherwise achieve clinical or commercial success, our regulatory strategy could be impaired, our ability to obtain regulatory approval could be delayed or prevented, or the market for our products may be reduced or eliminated, thereby harming or preventing our commercial success.

Even if we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the relative safety and efficacy of our product candidates, the actual or perceived quality of patient life while undergoing treatment with our product candidates, the ease with which our product candidates can be administered, the timing and scope of regulatory approvals for these product candidates, the availability and cost of manufacturing, marketing and sales capabilities, pricing, reimbursement coverage and patent positions, and the relative prioritization of our product candidates by physicians and healthcare providers among available therapies. Competing products and product candidates could present

superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products and product candidates may also make any product we develop obsolete or noncompetitive before we recover the expense of developing and commercializing such product. We could also face competition from other companies for collaboration partners, employees, advisors and service providers, which could negatively impact our ability to execute our business plans.

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Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive or more commercially viable than any products that we may develop. Furthermore, currently approved products could be discovered to have application for treatment of our targeted disease indications or similar indications, which could give such products significant regulatory and market timing advantages over our product candidates. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours and may obtain orphan product exclusivity from the FDA for indications that we are targeting, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, products or technologies developed by our competitors may render our product candidates uneconomical or obsolete and we may not be successful in marketing those product candidates, once approved, against competitors.

Our ability to compete effectively with other biotechnology and pharmaceutical companies depends on our ability to distinguish our company and our product candidates from our competitors and their product candidates.

Some of our competitors may have, or new competitors or alliances may emerge that have, greater name and brand recognition, greater market share, a larger customer base, more widely adopted proprietary technologies, greater marketing expertise, larger sales forces, or significantly greater resources than we do and may be able to offer solutions competitive with ours at a more attractive price than we can. Further, our current or potential competitors may be acquired by third parties with greater available resources. As a result, our competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards or customer requirements and may have the ability to initiate or withstand substantial price competition. In addition, our competitors may in the future establish cooperative relationships with vendors of complementary products, technologies or services to increase the availability of their solutions in the marketplace. Our competitors could also be better positioned to serve certain segments of our market, which could create additional price pressure. In light of these factors, even if any products that we may develop are more effective than those of our competitors, current or potential customers may accept competitive products in lieu of purchasing our products. If we are unable to successfully compete, our business, financial condition, and results of operations could be materially and adversely affected.

The loss of any member of our senior management team or our inability to attract and retain key personnel and consultants could adversely affect our business.

We may not be able to retain or attract qualified management, finance, scientific and clinical personnel and consultants due to the intense competition for a limited number of qualified personnel and consultants among biotechnology, pharmaceutical and other businesses. The loss of any members of our senior management team could adversely impact our operations if we experience difficulties in recruiting and hiring qualified successors. We may also experience difficulties in attracting or retaining personnel with sufficient experience and skills in the complex and emerging field of cellular therapeutic development and manufacture to support our ongoing and planned clinical development activities. We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. We may also be subject to penalties or other liabilities if we misclassify employees as consultants. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

Many of the biotechnology and pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources and different risk profiles than we do. We may be required to provide compensation in excess of historical levels in order to recruit and retain personnel in the current market. If we are not able to retain and attract necessary personnel and consultants to perform the requisite operational roles

personnel in the current market. If we are not able to retain and attract necessary personnel and consultants to perform the requisite operational roles

and accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our recent reduction in force undertaken to better align our workforce with the needs of our business and product pipeline prioritization may not achieve our intended outcome. 65

In January 2023, we announced a reduction in force affecting approximately 60% of our workforce to better align our workforce with the needs of our business and focus our capital resources on select product candidates, helping to provide that we are appropriately resourced into the second half of 2025. This 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 certain 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 or 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, our business, financial condition, and results of operations may be materially adversely affected.

Our business could be adversely affected by the effects of health pandemics or epidemics, including the COVID-19 pandemic, which could also cause significant disruption in the operations of CMOs, CROs, or other third parties upon whom we rely.

Our business has been, and could be, adversely affected by the effects of health pandemics or epidemics, which could also cause significant disruption in the operations of clinical trial sites, CMOs, CROs and other third parties upon whom we rely. For example, as

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a result of the ongoing COVID-19 pandemic, we have experienced disruptions to our supply chain, ongoing and future clinical trials and development of our product candidates.

In response to the COVID-19 pandemic, we implemented a remote work model for all employees except certain key essential members involved in business-critical activities. While most of our office-based employees have returned to the office under flexible work guidelines, a remote work model may need to be reinstated at some point in the future as the effects of the COVID-19 pandemic or other public health emergencies require. The effects of a remote and flexible work model may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, and could also increase our cybersecurity risk. We may also face challenges or disruptions upon a return back to the workplace, including re-integration challenges by our employees and distractions to management related to such transition.

Additionally, in response to COVID-19 or other future pandemics or epidemics, quarantines, stay at home orders, travel restrictions and other state and local restrictions on the conduct of business operations could occur, and any such restrictions could impact personnel at CMOs in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. Further, global public health concerns and pandemics, such as the COVID-19 pandemic, which caused a broad impact globally, may materially affect our financial condition and prospects.

The ultimate impact of the COVID-19 pandemic or a similar health pandemic or epidemic is highly uncertain, although any negative effects could have a material adverse impact on our operations, or the operations of third parties on whom we rely.

If we engage in an acquisition, reorganization or business combination, we will incur a variety of risks that could adversely affect our business operations or our stockholders.

From time to time, we have considered, and we will consider in the future, strategic business initiatives intended to further the expansion and development of our business. These initiatives may include acquiring businesses, technologies or products or entering into business combinations with other companies. If we pursue such a strategy, we could, among other things:

- issue equity securities that would dilute our current stockholders' percentage ownership;
- incur substantial debt that may place strains on our operations;
- spend substantial operational, financial and management resources to integrate new businesses, technologies and products;

- assume substantial actual or contingent liabilities;
- reprioritize our development programs and even cease development and commercialization of our product candidates; or
- merge with, or otherwise enter into a business combination with, another company in which our stockholders would receive cash or shares of the other company on terms that certain of our stockholders may not deem desirable.

Although we intend to evaluate and consider acquisitions, reorganizations and business combinations in the future, we have no agreements or understandings with respect to any acquisition, reorganization or business combination at this time.

We face potential product liability exposure far in excess of our limited insurance coverage.

The use of our product candidates in 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 participants in clinical trials, hospitals, medical centers, healthcare providers, pharmaceutical companies, and consumers, or by others selling, manufacturing or otherwise coming into contact with our product candidates. We carry product liability insurance and we believe our product liability insurance coverage is sufficient in light of our current clinical programs. In addition, if and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain insurance coverage for any approved products on commercially reasonable terms or in sufficient amounts to protect us against losses due to liability.

On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. In addition, under some of our agreements with clinical trial sites, we are required to indemnify the sites and their personnel against product liability and other claims. A successful product liability claim, or a series of claims, brought against us or any third parties whom we are required to indemnify could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Patients with the diseases targeted by our product candidates are often already in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for a variety of reasons. Such events, whether or not resulting from our product candidates, could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively

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affect or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our development and commercialization efforts, delay our regulatory approval process, or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

Our insurance policies are expensive and protect us from only some risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk to which our business is or may be exposed. Some of the policies we maintain include general liability, product liability, property, employee benefits liability, employment practices, workers' compensation, cyber, cybersecurity, directors' and officers' insurance, and umbrella. We do not know, however, if we will be able to maintain insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against losses. Even if we obtain insurance, a claim could exceed the amount of our insurance coverage or it may be excluded from coverage under the terms of the policy. Further, insurance coverage may not be available or successfully secured for loss profits or business interruption relating to the COVID-19 pandemic and its impacts. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

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Our employees or third party service providers may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee or third party service provider fraud or other misconduct. Misconduct by employees or third party service

providers could include intentional failures to comply with the regulations of the FDA or foreign regulators, to provide accurate information to the FDA or

foreign regulators, to comply with healthcare fraud and abuse laws and regulations in the United States and abroad, to report financial information or data accurately or to 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. Employee and independent contractor or third party service provider misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. If any actions alleging such conduct are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant effect on our business, including the imposition of significant fines or other sanctions.

Our business could be negatively affected by cyberattacks or a deficiency in our cybersecurity.

A cyberattack or similar incident could occur and result in information theft, data corruption, operational disruption, damage to our reputation, or financial loss. We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. Our technologies, systems, networks, or other proprietary information, and those of our vendors, suppliers and other business partners, may become the target of cyberattacks or information security breaches that could result in the unauthorized release, gathering, monitoring, misuse, loss, or destruction of proprietary and other information, or could otherwise lead to the disruption of our business operations. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Moreover, certain cyber incidents, such as surveillance, may remain undetected for an extended period and could lead to disruptions in critical systems or the unauthorized release of confidential or otherwise protected information. These events could lead to financial loss due to remedial actions, loss of business, disruption of operations, damage to our reputation, or potential liability. Our systems and insurance coverage for protecting against cybersecurity risks may not be sufficient. Furthermore, as cyberattacks continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any vulnerability to cyberattacks.

We face risks of potential liability related to the privacy of personal information, including health information we utilize in the development of our products, as well as information we obtain from clinical trials sponsored by us from research institutions and directly from individuals.

We and our partners and vendors may be subject to various federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators, including HIPAA the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) and privacy and security requirements under HIPAA, as amended by HITECH. the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH). Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Even when HIPAA does not apply, failing to take appropriate steps to keep consumers' personal information secure may constitute a violation of the Federal Trade Commission Act. In addition, certain of the materials we use as starting material in our iPSC-derived product candidates are derived from human sources, which potentially contain sensitive identifiable personal information regarding the donor. In addition, in conducting our clinical trials, we may maintain sensitive identifiable personal information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our clinical trials. As such, we may become subject to further obligations under HIPAA. Our collection of personal information generally (e.g., of employees currently and/or of patients in the future) may subject us to state data privacy laws governing the processing of personal information and requiring notification of affected individuals and state regulators in the event of a breach of such personal information. These state laws include the CCPA and its related regulations, and California Consumer Privacy Act , as amended by the CPRA amending the CCPA, California Privacy Rights Act (the CCPA), which establish additional data privacy rights for residents of the State of California, with corresponding obligations on businesses related to transparency, deletion rights, and opt-out of the selling or sharing of personal information, and grants a private right of action for individuals in the event of certain security breaches. Similar laws relating to data privacy and security have passed in several other states, which may

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privacy and security have been proposed in other states and at the federal level, and if passed, such laws may have potentially conflicting requirements that would make compliance challenging, require us to expend significant resources to come into compliance, and restrict our ability to process certain personal information.

Certain state laws may be more stringent or broader in scope than the CPRA, CCPA, or offer greater individual rights, with respect to confidential, sensitive and personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts.

An increasing number of foreign data protection laws, regulations and industry standards may also apply to personal information we obtain from individuals outside of the United States. For example, the GDPR, imposes strict requirements for processing the personal data of individuals within the EEA and UK, including health-related data, and on the transfer of personal data out of the EEA and UK to non-adequate territories such as the United States; any inability to transfer personal data from the EEA and UK to the United States in compliance with data protection laws may impede our ability to conduct trials and may adversely affect our business and financial position. Failure to comply with the requirements of the GDPR may result in potential fines for companies of up to the greater of €20 million (£17.5 million for the UK GDPR) or 4% of annual global revenue and other administrative penalties. In addition, under the GDPR, companies may face private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to protect their interests. Although the EU GDPR and the UK GDPR currently impose substantially similar obligations, it is possible that over time the UK GDPR could become less aligned with the EU GDPR, particularly with the introduction of the new Data Reform Bill into the UK legislative process. In addition, EEA Member States have adopted national laws to supplement the EU GDPR, which may partially deviate from the EU GDPR, and the competent authorities in the EEA Member States may interpret EU GDPR obligations slightly differently from country to country, such that we do not expect to operate in a uniform legal landscape in the EEA and UK with respect to data protection regulations. The potential of the respective provisions and enforcement of the EU GDPR and UK GDPR further diverging in the future creates additional regulatory challenges and uncertainties for us. The lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, uncertainty, complexity and compliance cost to the handling of European personal data and our privacy and data security compliance, and could require us to amend our processes and procedures to implement different compliance measures for the UK and the EEA.

We are likely to be required to expend significant capital and other resources to ensure ongoing compliance with applicable data privacy and security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend, and could result in adverse publicity that could harm our business. Moreover, even if we take all necessary action to comply with legal and regulatory requirements, we could be subject to a data breach or other unauthorized access of personal information, which could subject us to fines and penalties, as well as litigation and reputational damage. If we fail to keep apprised of and comply with applicable international, federal, state, or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or any collaborators' ability to seek to commercialize our clinical candidates. Any threatened or actual government enforcement action or litigation where private rights of action are available could also generate adverse publicity, damage our reputation, result in liabilities, fines and loss of business, and require that we devote substantial resources that could otherwise be used in other aspects of our business.

We make public statements about our use and disclosure of personal information through our privacy policy information provided on our internet platform and press statements. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be alleged to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees or contractual partners fail to comply with our published policies, certifications and documentation. The publication of our privacy policy and other statements that provide promises and assurances about data privacy and security can subject us to potential government or legal action if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any failure, real or perceived, by us to comply with our posted privacy policies or with any legal or regulatory requirements, standards, certifications or orders or other privacy or consumer protection-related laws and regulations applicable to us could cause our customers to reduce their use of our products and services and could materially and adversely affect our business, financial condition and results of operations. In many jurisdictions, enforcement actions and consequences for non-compliance can be significant and are rising. In addition, from time to time, concerns may be expressed about whether our products, services or processes compromise the privacy of customers and others. Concerns about our practices with regard to the collection, use, retention, security, disclosure, transfer and other processing of personal information or other privacy-related matters, even if unfounded, could damage our reputation and materially and adversely affect our business, financial condition and results of operations.

Many statutory requirements, both in the United States and abroad, include obligations for companies to notify individuals of security breaches involving certain personal information, which could result from breaches experienced by us or our third-party service providers. For example, laws in all 50 U.S. states and the District of Columbia require businesses to provide notice to consumers whose sensitive personal information has been disclosed as a result of a data breach. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. Moreover, states have been frequently amending existing laws, requiring attention to changing regulatory requirements. We also may be contractually required to notify customers or other counterparties of a security breach. Although we may have contractual protections with our third-party service providers, contractors and consultants, any actual or perceived security breach could harm our reputation and brand, expose us to potential

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liability or require us to expend significant resources on data security and in responding to any such actual or perceived breach. breach or security incident. Any contractual protections we may have from our third-party service providers, contractors or consultants may not be sufficient to adequately protect us from any such liabilities and losses, and we may be unable to enforce any such contractual protections.

In addition to the possibility of fines, lawsuits, regulatory investigations, public censure, other claims and penalties, and significant costs for remediation and damage to our reputation, we could be materially and adversely affected if legislation or regulations are expanded in a manner that requires changes in our data processing practices and policies or if governing jurisdictions interpret or implement their legislation or regulations in ways that negatively impact our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Any inability to adequately address data privacy or security-related concerns, even if unfounded, or to comply with applicable laws, regulations, standards and other obligations relating to data privacy and security, could result in additional cost and liability to us, harm our reputation and brand, damage our relationships with contract partners and the physician and patient community and have a material and adverse impact on our business.

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Our internal computer systems, or those used by our third-party research institution collaborators, CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors, vendors, and consultants may be vulnerable to damage from cyber cybersecurity risks, including attempts to gain unauthorized access to and to harm sensitive or confidential information and networks, insider threats, and ransomware. These vulnerabilities may be heightened as a result of flexible work arrangements, including hybrid or remote work policies implemented by us and our third-party contractors, that were first adopted in response to the COVID-19 pandemic.pandemic and have continued by many businesses in an effort to attract and retain talent.

We have from time to time experienced, and may continue to experience in the future, cyber-attacks on our information technology systems despite our best efforts to prevent them. Although such breaches incidents have been immaterial to our business to date, investigations into and remedial efforts in connection with any breaches, security incidents, even those with immaterial impact, can be costly and time-consuming, and any future breaches incidents could be material, or cause significant disruption, to our business. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for research and development, the manufacture and supply of drug product and drug substance and to conduct clinical trials. We depend on these third parties to implement adequate controls and safeguards to protect against and report cyber cybersecurity incidents. If they fail to do so, we may suffer financial and other harm, including to our information, operations, performance, and reputation. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

Cyber Cybersecurity threats, both on premises and in the cloud, are evolving and include, but are not limited to: malicious software, destructive malware, ransomware, attempts to gain unauthorized access to systems or data, disruption to operations, critical systems or denial of service attacks; unauthorized release of confidential, personal or otherwise protected information; corruption of data, networks or systems; harm to individuals; and loss of assets. In addition, we could be impacted by cyber cybersecurity threats or other disruptions or vulnerabilities found in products or services we use that are provided to us by third-parties. The techniques used by criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. These events, if not prevented or effectively mitigated, could damage our reputation, require remedial actions and lead to loss of business, regulatory actions, potential liability and other financial losses.

Certain data breaches must also be reported to affected individuals and various government and/or regulatory agencies, and in some cases to the media, under provisions of HIPAA, as amended by HITECH, other U.S. federal and state law, and requirements of non-U.S. jurisdictions, including the European Union Data Protection Directive, and financial penalties may also apply.

Our insurance policies may not be adequate to compensate us for the potential losses arising from breaches, failures or disruptions of our infrastructure, catastrophic events and disasters or otherwise. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and defending a suit, regardless of its merit, could be costly and divert management's attention

and divert management's attention.

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Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, 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 of these factors. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those 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 product candidates to be reviewed and/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 and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, 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, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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Risks Related to Our Financial Condition and the Ownership of Our Common Stock

Our ongoing and planned operations, including the development of our product candidates, will require substantial additional funding, without which we will be unable to complete preclinical or clinical development of, or obtain regulatory approval for, our product candidates.

We are currently advancing multiple product candidates through clinical development, and conducting preclinical research and development activities in our other programs. Drug development is expensive, and we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance our current product candidates in clinical trials and seek to initiate clinical development for additional product candidates.

As of December 31, 2022, our cash and cash equivalents and investments were $441.2 million. We intend to use our cash and cash equivalents and investments primarily to fund the advancement and clinical development of our current product candidates and our ongoing preclinical, discovery and research programs, and for working capital and general corporate purposes. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic and licensing arrangements or a combination of these approaches. In any event, we will require additional capital to obtain regulatory approval for, and to commercialize our existing product candidates and any other product candidates we may identify and develop. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Our future capital requirements will depend on many factors, including, but not limited to:

- the progress, results, size, timing and costs of our ongoing and planned clinical trials, and any additional clinical trials we may initiate, conduct or support for our product candidates;
- the progress, results, size, timing and costs of our preclinical, process development and manufacturing studies, and activities necessary to initiate and conduct clinical trials for our product candidates and to establish and maintain manufacturing capabilities necessary to support such trials;
- continued progress in our research and development programs, including preclinical studies, process development, manufacturing and other research activities that may be necessary in order for an IND application to go into effect for a prospective clinical development candidate, as well as potential future clinical trials of any additional product candidates we may identify for development;

- the extent to which we are required to pay milestone or other payments under our existing in-license agreements and any in-license agreements that we may enter into in the future, and the timing of such payments, including payments owed to MSK in connection with the stock price appreciation milestones;
- our ability and the ability of our investigators to initiate and conduct, and the progress, results, size, timing and costs of, clinical trials of our product candidates that will be necessary to support any application for regulatory approval;
- our ability to manufacture, or enter into arrangements with third parties for the manufacture of our existing product candidates, as well as potential future clinical development candidates, both for clinical development and commercialization, and the timing and costs associated with such manufacture;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, or other costs we may incur, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the cost of manufacturing, distribution, and commercialization activities and arrangements, including the manufacturing of our product candidates, establishment of effective protocols for the supply and transport of our product candidates, and the establishment of a sales and marketing organization either internally or in partnership with a third party; and
- our ability to establish and maintain strategic arrangements and alliances with third-party collaborators including our existing collaborations with Ono, the University of Minnesota, and MSK, to advance the research, development and commercialization of therapeutic products.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment and interest obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to

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acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at a different stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. In addition, while the overall impacts of the COVID-19 pandemic and the ongoing conflict in Ukraine on the global economy remain unknown and difficult to predict, these events caused significant disruptions and created uncertainties in the global financial markets, and the economic impacts of these and other similar global events could materially and adversely affect our ability to raise capital through equity or debt financings in the future.

If we cannot raise additional capital or obtain adequate funds, we may be required to curtail significantly our research and clinical programs or may not be able to continue our research or clinical development of our product candidates. Our failure to raise additional capital, or obtain adequate funds, will have a material adverse effect on our business, prospects, financial condition, results of operations, and market price of shares of our common stock.

We have a limited operating history, have incurred significant losses since our inception, and anticipate that we will continue to incur significant losses for the foreseeable future.

We are a clinical-stage biopharmaceutical company formed in 2007 with a limited operating history. We have not yet obtained regulatory approval for any of our product candidates or generated any revenues from therapeutic product sales. Since inception, we have incurred significant net losses in each year and, as of December 31, 2022, we had an accumulated deficit of $1.05 billion. We expect to continue to incur losses for the foreseeable future as we continue to fund our ongoing and planned clinical trials of our product candidates, and our other ongoing and planned research and development activities. We also expect to incur significant operating and capital expenditures as we continue our research and development of, and seek regulatory approval for, our product candidates, in-license or acquire new product candidates for development, implement additional infrastructure and internal systems, and hire additional scientific, clinical, and administrative personnel. We anticipate that our net losses for the next several years could be significant as we conduct our planned operations.

Because of the numerous risks and uncertainties associated with pharmaceutical, biological, and cell therapy product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. In addition, our expenses could increase if we are required by the FDA, or comparable foreign regulatory authorities, to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical trials, preclinical studies, process development, manufacturing activities, or the research and development of any of our product candidates. The amount of our future net losses will depend, in part, on the rate of increase in our expenses, our ability to generate revenues and our ability to raise additional capital. These net losses have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

Our stock price is subject to fluctuation based on a variety of factors.

The market price of shares of our common stock could be subject to wide fluctuations as a result of many risks listed in this section, and other risks beyond our control, including:

- the timing of the initiation of, and progress in, our current and planned clinical trials;
- the results of our clinical trials and preclinical studies, and the results of clinical trials and preclinical studies by others for product candidates or indications similar to ours;
- developments related to the FDA or to regulations applicable to cellular immunotherapies generally or our product candidates in particular including, but not limited to, regulatory pathways and clinical trial requirements for approvals;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments, such as our recent announcement of the termination of our collaboration with Janssen;
- developments related to proprietary rights including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key management or scientific personnel;
- actual or anticipated changes in our research and development activities and our business prospects, including in relation to our competitors;
- developments of technological innovations or new therapeutic products by us or others in the field of immunotherapy;
- announcements or expectations of additional equity or debt financing efforts;

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- sales of our common stock by us or by our insiders or our other stockholders;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- comments by securities analysts;
- fluctuations in our operating results (including changes related to stock-based compensation from performance-based awards);
- acts of war or periods of widespread civil unrest, including the increasingly volatile global economic conditions resulting from the conflicts in Ukraine; ongoing wars between Russia and Ukraine and between Israel and Hamas; and
- general economic and market conditions, including inflationary pressures and stock market volatility.

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These and other market and industry factors, including the effects of the COVID-19 pandemic, any future public health crises or other public health concerns, wars or armed conflicts, including the ongoing conflict wars between Russia and Ukraine and between Israel and Hamas, the upcoming presidential election in Ukraine, the U.S. or similar events, and global economic conditions, may cause the market price and demand for our common stock to fluctuate substantially regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock.

Changes in our stock price may also trigger financial obligations under our licensing arrangements. For example, pursuant to the terms of our license agreement with MSK, MSK the Amended MSKCC License, MSKCC is eligible to receive from us certain milestone payments totaling up to $75.0 million based on the price of our common stock, where the amount of such payments owed to MSK MSKCC is contingent upon certain increases in the price of our common stock following the date of achievement of a specified clinical milestone. In July 2021, we achieved the specified clinical milestone for a licensed product under our license agreement with MSK the Amended MSKCC License and our ten-trading day trailing average common stock price exceeded the first, pre-specified threshold. Accordingly, MSK MSKCC received the first milestone payment of $20.0 million in November 2021; however, uncertainty of the price of our common stock results in an inability to ascertain the precise timing of any remaining future milestone payments in advance.

Additionally, a decrease in our stock price may cause our common stock to no longer satisfy the continued listing standards of Nasdaq. If we are not able to maintain the requirements for listing on Nasdaq, our common stock could be delisted, which could have a materially adverse effect on our ability to raise additional funds as well as the price and liquidity of our common stock.

Our principal stockholders and management own a significant percentage of our stock and may be able to exercise significant control over

our company.

As of February 22, 2023 February 20, 2024, our executive officers, directors and entities affiliated with our five percent stockholders beneficially own, in the aggregate, shares representing approximately 56.5% 54.8% of our outstanding voting stock. If, in accordance with the CoD (as such term is defined in Note 9 of the notes to the consolidated financial statements herewith) relating to the Class A Convertible Preferred Stock, Redmile (as such term is defined in Note 9 of the notes to the consolidated financial statements herewith) elects to remove certain limitations on the percentage of the our outstanding common stock that it may own such that the 2,794,549 2,761,108 shares of Class A Convertible Preferred Stock currently held by Redmile become fully convertible at Redmile's option into 13,972,745 13,805,540 shares of common stock, the beneficial ownership of our executive officers, directors and entities affiliated with our five percent stockholders would increase to 61.8% 59.4%. Although we are not aware of any voting arrangements in place among these stockholders, if these stockholders were to choose to act together, as a result of their stock ownership, they would be able to influence our management and affairs and control all matters submitted to our stockholders for approval, including the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership may have the effect of delaying or preventing a change in control of our company that our other stockholders may believe are in their best interests, or adversely affecting the liquidity, volatility, and market price of our common stock. For example, if any of our directors, executive officers or other entities affiliated with our five percent stockholders elect to sell, transfer or otherwise dispose of a significant amount of shares of our common stock, this could result in a decrease in our stock price. Furthermore, any transferees or successors of all or a significant portion of our existing stockholders' ownership in us will be able to exert a similar amount of control over us through their ownership position.

We may sell additional equity or debt securities or enter into other arrangements to fund our operations, which may result in dilution to our stockholders and impose restrictions or limitations on our business.

We expect that significant additional capital will be needed in the future to continue our planned operations, and we may seek additional funding through a combination of equity offerings, debt financings, state or government grants, strategic alliances, licensing and collaboration arrangements, or other third-party business arrangements. These financing activities may have an adverse effect on our stockholders' rights, the market price of our common stock and on our operations and may require us to relinquish rights to some of our technologies, intellectual property or product candidates, issue additional equity or debt securities, or otherwise agree to terms unfavorable to us. Further, in November 2021 2023, we filed a registration statement on Form S-3 pursuant to which we may issue and sell up to $350.0 million $300.0 million in common stock, preferred stock, debt securities, warrants and/or units, in one or more series or classes, including up to $100.0 million in shares of common stock that may be issued in sales deemed to be an "at the market offering" as defined by the Securities Act of 1933, as amended (the Securities Act) and, so long as we qualify as a "well-known seasoned issuer" as defined in Rule 405 of the Securities Act, an unlimited amount of shares of our common stock, preferred stock, debt securities, warrants and/or units. . Any sale or issuance

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of securities pursuant to a registration statement or otherwise may result in dilution to our stockholders and may cause the market price of our stock to decline, and new investors could gain rights superior to our existing stockholders. In addition, any debt financings that we may enter into in the future may subject us to unfavorable repayment terms, including increased interest rates, impose restrictive covenants or otherwise adversely affect the holdings or the rights of our stockholders, and any additional equity financings will be dilutive to our stockholders. Furthermore, additional equity or debt financing might not be available to us on reasonable terms, if at all.

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A significant portion of our total outstanding shares may be sold into the market in the near future, which could cause the market price of our common stock to drop significantly.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. A significant portion of our outstanding shares of common stock are held by a small number of stockholders, including our directors, officers and significant stockholders. Sales by our stockholders of a substantial number of shares, or the expectation that such sales may occur, could significantly reduce the market price of our common stock.

For example, we registered all of the 5,250,000 shares of common stock issued by us in our August 2016 private placement transaction for resale on a Form S-3, which was declared effective by the SEC in September 2016. We also registered all of the 6,766,915 shares of common stock

issued by us and all 14,097,745 shares of common stock issuable upon the conversion of an aggregate of 2,819,549 shares of Class A Convertible

Preferred Stock issued by us in our November 2016 private placement transaction for resale on a Form S-3, which was declared effective by the SEC in January 2017. Additionally, we have registered the shares of common stock issued to Johnson & Johnson Innovation – JJDC, Inc. under a the stock purchase agreement entered into in June 2020 in connection with the Janssen Agreement pursuant to a registration statement on Form S-3. Moreover, we registered all of the 5,380,117 shares of common stock issued by us and all of the 257,310 prefunded warrants to purchase common stock in our public offering in January 2021.

We have also registered or intend to register all shares of our common stock subject to options, restricted stock units or other equity awards issued or reserved for future issuance under our equity incentive plans. As a result, these shares will be available for sale in the public market subject to vesting arrangements and exercise of options, and restrictions under applicable securities laws. In addition, certain of our executive officers, employees and affiliates have established or and may in the future establish programmed selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended, for the purpose of effecting sales of our common stock. If any of these events cause a large number of our shares to be sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

We have broad discretion over the use of our cash, cash equivalents, and investments and may not use them effectively.

Our management has broad discretion to use our cash, cash equivalents, investments and any additional funds that we may raise to fund our operations and could spend these funds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline or delay the development of our product candidates. We may invest our cash and cash equivalents in a manner that does not produce income or that loses value.

Provisions of Delaware law or our charter documents could delay or prevent an acquisition of our company, and could make it more difficult for you to change management.

Provisions of Delaware law, our amended and restated certificate of incorporation, and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions may also prevent or delay attempts by stockholders to replace or remove our current management or members of our board of directors. These provisions include:

- a classified board of directors with limitations on the removal of directors;
- advance notice requirements for stockholder proposals and nominations;
- the inability of stockholders to act by written consent or to call special meetings;
- the ability of our board of directors to make, alter or repeal our amended and restated bylaws; and
- the authority of our board of directors to issue preferred stock with such terms as our board of directors may determine.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge

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or combine with us. Any provision of our amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or discouraging a potential acquisition proposal or tender offer could limit the opportunity for our stockholders to achieve liquidity for their shares of our common stock, even if the acquisition proposal or tender offer is at a premium over the then-current market price for our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated bylaws designate the Court of Chancery of the State of Delaware and the U.S. federal district courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to litigate disputes with us in a different judicial forum.

Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, or employees to us or our stockholders; (iii) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware, our

amended and restated certificate of incorporation or our amended and restated bylaws; or (iv) any action asserting a claim governed by the internal affairs doctrine. This exclusive forum provision will not apply to any causes of action arising under the Securities Act. Unless we consent in writing to the selection of an alternate forum, the U.S. federal district courts shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. The forum selection clause in our amended and restated bylaws may limit our stockholders' ability to litigate disputes with us in a different judicial forum.

Our ability to use our net operating loss carryforwards and certain other tax benefits may be limited and, as a result, our future tax liability may increase.

As of December 31, 2022 December 31, 2023, we had federal and California net operating loss carryforwards of $392.5 million $526.4 million and $452.2 million $522.1 million, respectively, some of which begin to expire in various amounts in 2027 and 2028, respectively. As of December 31, 2022 December 31, 2023, we also had federal and California research and development tax credit carryforwards of $35.1 million $40.3 million and $33.3 million $34.7 million, respectively. The federal research and development tax credit carryforwards will begin to expire in 2035 unless previously utilized, while the California carryforwards will carry forward indefinitely. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses (NOLs) or tax credits, or NOLs or credits, to offset future taxable income or taxes. Generally, a change of more than 50 percentage points in the ownership of a corporation's stock, by value, over a three-year period constitutes an ownership change for U.S. federal income tax purposes. We have determined that we triggered an ownership change limitation in November 2009 and again in May 2015. We have determined that we do not believe there were any ownership changes from May 2015 through December 2022. 2023. We have not analyzed periods subsequent to December 2022. 2023. We may experience additional ownership changes as a result of shifts in our stock ownership in the future. Limits on our ability to use our pre-change NOLs or credits to offset U.S. federal taxable income could potentially result in increased future tax liability to us if we earn net taxable income in the future. The amount of NOLs generated in taxable periods beginning after December 31, 2022 December 31, 2023, that we are permitted to deduct in any taxable year is limited to 80% of our taxable income in such year, where taxable income is determined without regard to the NOL deduction itself. U.S. federal and certain state NOLs generated in taxable years beginning after December 31, 2017 are not subject to expiration.

General Risk Factors

We are and could be further subject to securities class action litigation and other types of stockholder litigation.

The stock market in general, and the Nasdaq Global Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. For example, in January 2023, a purported stockholder filed a lawsuit against us and certain of our officers captioned Hadian v. Fate Therapeutics, Inc. et al. in the U.S. District Court for the Southern District of California and in June 2023, a derivative action was filed in the same court (see *"Item 3. Legal Proceedings"*) for a more detailed description of this matter). We could also be subject to other types of litigation, which may involve claims of breach of fiduciary duties by our directors or officers for misuse/mismanagement of company assets/resources or conflicts of interest. Any such litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results, or financial condition. Additionally, the dramatic increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements, and damages awarded to plaintiffs.

Our business operations may subject us to disputes, claims and lawsuits, which may be costly and time-consuming and could materially and adversely impact our financial position and results of operations.

From time to time, we may become involved in disputes, claims and lawsuits relating to our business operations. For example, we have in the past and we may, from time to time, face or initiate claims related to intellectual property matters, employment matters, or commercial disputes. Any dispute, claim or lawsuit may divert management's attention away from our business, we may incur significant expenses in addressing or defending any dispute, claim or lawsuit, and we may be required to pay damage awards or settlements or become subject to equitable remedies that could adversely affect our operations and financial results. Litigation related to these disputes may be costly and time-consuming and could materially and adversely impact our financial position and results of operations if resolved against us. In addition, the uncertainty associated with litigation could lead to increased

impact our financial position and results of operations if resolved against us. In addition, the uncertainty associated with litigation could lead to increased volatility in our stock price.

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

Our ability to invest in and expand our business and meet our financial obligations, to attract and retain third-party contractors and collaboration partners and to raise additional capital depends on our operating and financial performance, which, in turn, is subject to numerous factors, including the prevailing economic and political conditions and financial, business, regulatory and other factors beyond our control, such as the rate of unemployment, rate of inflation, the number of uninsured persons in the United States, political influences and inflationary pressures, and fluctuations in costs, particularly due to changes in labor costs and material costs. For example, an overall decrease in or loss of insurance coverage among individuals in the United States due to high levels of unemployment, (particularly as a result of the COVID-19 pandemic), underemployment or the repeal of certain provisions of the ACA may decrease the demand for healthcare services and pharmaceuticals. If fewer patients are seeking medical care because they do not have insurance coverage or are unable to obtain medical care for their conditions due to resource constraints on the healthcare system, we may experience difficulties in any eventual commercialization of our product candidates and our business, results of operations, financial condition and cash flows could be adversely affected. In addition, if we are unable to manage cost fluctuations and inflationary pressures, including prices of materials, costs of labor, it may adversely impact our operating performance, expenses and results.

In addition, our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets upon which pharmaceutical and biopharmaceutical companies such as us are dependent for sources of capital. In the past, global financial crises have caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, wars or armed conflicts, including as a result of the COVID-19 pandemic, the ongoing conflict in wars between Russia and Ukraine and between Israel and Hamas, interest rate fluctuations, rising inflations or recession, could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all, and weakened demand for our product candidates. A weak or declining economy, and rising inflation could also strain our suppliers, possibly resulting in supply disruption. Additionally, the upcoming 2024 U.S. Presidential election could cause additional legal, political and economic uncertainty. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the COVID-19 pandemic, the ongoing conflict in Ukraine, wars and conflicts, current economic climate and financial market conditions could adversely impact our business.

Volatility in capital markets and lower market prices for our securities may affect our ability to access new capital through sales of shares of our common stock or issuance of indebtedness, which may harm our liquidity, limit our ability to grow our business, pursue acquisitions or improve our operating infrastructure and restrict our ability to compete in our markets.

Our operations consume substantial amounts of cash, and we intend to continue to make significant investments to support our business growth, respond to business challenges or opportunities, develop new product candidates, retain or expand our current levels of personnel, improve our existing products, enhance our operating infrastructure, and potentially acquire complementary businesses and technologies. Our future capital requirements may be significantly different from our current estimates and will depend on many factors, including the need to:

- finance unanticipated working capital requirements;
- continue the research and development or our existing product candidates and develop or enhance our technological infrastructure;
- pursue acquisitions, in-licenses or other strategic relationships; and
- respond to competitive pressures.

Accordingly, we may need to pursue equity or debt financings to meet our capital needs. With uncertainty in the capital markets and other factors, such financing may not be available on terms favorable to us or at all. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our common stock. Any debt

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financing secured by us in the future could involve additional restrictive covenants relating to our capital-raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. If we are unable to obtain adequate financing or financing on terms satisfactory to us, we could face significant limitations on our ability to

acquisitions. If we are unable to obtain adequate financing or financing on terms satisfactory to us, we could face significant limitations on our ability to invest in our operations and otherwise suffer harm to our business.

Recent increases in interest rates could affect our ability to obtain working capital through borrowings such as bank credit lines and public or private sales of debt securities, which may result in lower liquidity, reduced working capital and other adverse impacts on our business.

To meet our liquidity needs, we have previously relied, in part, on borrowed funds, and may do so again in the future. Continued increases in interest rates will increase the cost of new indebtedness and could materially and adversely affect our results of operations, financial condition, liquidity and cash flows.

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Increasing scrutiny and changing expectations from governments and third-parties relating to environmental, social and governance (ESG) policies and practices may cause us to incur additional costs or expose us to additional risks.

In recent years, there has been increasing public focus and scrutiny from certain investors, employees and other stakeholders concerning corporate responsibility, specifically related to ESG factors. Third-party providers of ESG ratings and reports on companies have increased in number, resulting in varied and, in some cases, inconsistent standards and frameworks. Topics taken into account in such assessments include, among others, our efforts and impacts with respect to climate change and the role of our board of directors in supervising various sustainability issues.

Some investors may use third-party ESG ratings and reports to guide their investment strategies and, in some cases, may choose not to invest in us if they believe our ESG practices are inadequate. At the same time, anti-ESG sentiment has gained some momentum across the United States, with several states having enacted or proposed “anti-ESG” policies or legislation, which may conflict with other laws or regulations. The criteria by which companies’ ESG practices are assessed are evolving, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Alternatively, if we elect not to or are unable to satisfy new criteria or do not meet the criteria of a specific third-party provider, some investors may conclude that our policies with respect to ESG are inadequate and choose not to invest in us.

If our ESG practices do not meet evolving investor, government agency or other stakeholder expectations and standards, then our reputation, our ability to attract or retain employees and the market price of our securities could be negatively impacted. New governmental regulations could result in new directives and new or more stringent forms of ESG oversight and disclosures which may lead to increased expenditures for sustainability initiatives, which in turn could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common stock to decline.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and its financial condition and results of operations.

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, on March 10, 2023, Silicon Valley Bank (SVB) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (FDIC) as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. In these cases borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. We currently use deposit accounts to fund our operations and other financial instruments such as cash-collateralized letters of credit associated with our facilities leases. Our excess cash is invested according to a restrictive investment policy within custodial accounts at various financial institutions. If any of the financial institutions that hold our deposit accounts were to be placed into receivership, we may be unable to access the funds in those accounts, which could result in liquidity constraints or failures. In addition, if any of our collaboration partners, suppliers or other parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties’ ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. In this regard, counterparties to SVB credit agreements and arrangements, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure of SVB, or the sale of its assets, and uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis.

Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities. Although the U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions

secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments,

widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. Additionally, there is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although we assess our banking and other business relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements 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 credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions

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with which we have financial or business relationships but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; or
- Delayed or lost access to, or reductions in borrowings available under working capital sources and/or delays, inability or reductions in our ability to refund, roll over or extend the maturity of, or enter into new working capital resources.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws.

Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our collaboration partners, suppliers or other parties with whom we do business, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. Any bankruptcy or insolvency of a collaboration partner, supplier or other party with whom we do business, or the failure of any such party to make payments when due, or any breach or default by any such party, or the loss of any significant commercial relationships, could result in material losses to us and may have a material adverse impact on our business.

Geopolitical risks associated with ongoing wars and conflicts, including the ongoing military conflict wars between Russia and Ukraine and between Israel and Hamas, could have an adverse impact on our business, financial condition and results of operations, including our clinical trials.

In February 2022, There are ongoing conflicts, including the wars between Russia commenced a military invasion of and Ukraine and sustained conflict between Israel and disruption in Hamas, and although the region is likely. Although the conflict has conflicts have had little direct impact on our business to date, the uncertainty and ripple effects created by this conflict these conflicts may have unknown indirect impacts. For instance, the ongoing conflict has conflicts have resulted in significant volatility in certain equity, debt and currency markets, material increases in certain commodity prices, and economic uncertainty. It is not possible to predict the broader or longer-term consequences of this conflict, these conflicts, although a prolonged conflict may result in adverse effects on microeconomic conditions including inflation; disruptions to our global technology infrastructure, including through cyberattack, ransom attack, or cyber-intrusion; cybersecurity-intrusion; adverse changes in international trade policies and relations; disruptions in global supply chains; our exposure to foreign currency fluctuations; and constraints, volatility, or disruption in the capital markets, any of which could negatively impact our business, financial performance and financial condition. Sanctions imposed by the U.S., United States, Canada, EU, and other countries in response to the conflict between Russia and Ukraine ongoing conflicts and the potential response to such sanctions may also have an adverse impact our business, including our clinical trials, the financial markets and the global economy

adverse impact our business, including our clinical trials, the financial markets and the global economy.

We continue to monitor any adverse impact that the outbreak of war in Ukraine and the subsequent institution of sanctions against Russia by the United States and other countries may have on the global economy in general, on our business and operations and on the businesses and operations of our suppliers and third parties with whom we conduct business.

We or the third parties upon whom we depend may be adversely affected by earthquakes, fires, or other natural disasters, including epidemics and pandemics such as COVID-19, public health crises, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Earthquakes, fires, or other natural disasters (including due to the effects of climate change or any public health crises) could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our manufacturing facilities or those of our CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. For example, as a result of the COVID-19 pandemic, we may experience delays or disruptions in our clinical development activities, our research and development activities, and in the supply of drug product or other materials and components necessary to conduct our clinical trials. Any continued or subsequent Further, any measures taken by governmental authorities or businesses in response to contain the spread of COVID-19, any public health crisis, such as quarantines, stay-at-home orders or the perception that such measures may be required in the future should another outbreak occur, travel restrictions, could adversely affect our business, operations, financial condition, prospects or results of operations by restricting our ability to conduct our clinical trials and research and development activities, and limiting our and our third-party manufacturers' ability to manufacture product and forcing temporary closure of our facilities and facilities that we rely

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upon. The disaster recovery and business continuity plans we have in place currently are limited and may not prove adequate for protecting and continuing our business in the event that our business is disrupted as a result of the COVID-19 pandemic a public health crisis or other serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

If we fail to maintain an effective system of disclosure controls and procedures and internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.

As a public company, we are required to comply with the Sarbanes-Oxley Act of 2002, as amended (the Sarbanes-Oxley Act), and the related rules and regulations of the SEC, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing and maintaining

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corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud.

We cannot assure that we will not have material weaknesses or significant deficiencies in our internal control over financial reporting. If we are unable to successfully remediate any material weakness or significant deficiency in our internal control over financial reporting, or identify any material weaknesses or significant deficiencies that may exist, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, and our stock price may decline materially as a result.

If we fail to comply with environmental, health, and safety laws and regulations, including regulations governing the handling, storage or disposal of hazardous materials, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment, and disposal of hazardous materials and wastes. Our operations involve the use of hazardous materials, including chemicals, biological materials and infectious agents. Our operations also may produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We will not be able to eliminate the risk of contamination or injury from these materials. In the

parties for the disposal of these materials and wastes. We will not be able to eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from any use by us of 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 regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous 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.

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations. These current or future laws and regulations may impair our research, development, or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Changes in tax law may adversely affect us or our investors.

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 or IRS, (IRS) and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, the Tax Cuts and Jobs Act was enacted in 2017 and made significant changes to corporate taxation, including the reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, the limitation of the tax deduction for net interest expense to 30% of adjusted taxable income (except for certain small businesses), the limitation of the deduction for net operating losses to 80% of current year taxable income and the elimination of net operating loss carrybacks (though any such net operating losses may be carried forward indefinitely), and the modification or repeal of many business deductions and credits. In addition, under Section 174 of the Internal Revenue Code of 1986, as amended, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the U.S. will be capitalized and amortized, which may have an adverse effect on our cash flow. It cannot be predicted whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law.

Our business could be negatively impacted by corporate citizenship and environmental, social and corporate governance matters and/or our reporting

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There is an increasing focus from certain investors, consumers, and other stakeholders concerning corporate citizenship and sustainability matters. We could be perceived as not acting responsibly in connection with these matters. Our business could be negatively impacted by such matters. Any such matters, or related corporate citizenship and sustainability matters, could have a material adverse effect on our business.

ITEM 1B. Unresolved Staff Comments

Not Applicable.

 ITEM 1C. Cybersecurity

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We have implemented and maintain a cybersecurity risk management program that includes processes for the identification, assessment, and mitigation of cybersecurity risks. We conduct annual cybersecurity training for all of our employees and periodically engage third-party consultants to conduct penetrating testing and vulnerability assessments. Additionally, we use automated tools designed to monitor, identify, and address cybersecurity risks. Further, we have a process to evaluate and review the cybersecurity practices of our key vendors prior to onboarding, including through a general security assessment and contractual requirements, as appropriate.

We face a number of cybersecurity risks in connection with our business. Although such risks have not materially affected us, including our business strategy, results of operations or financial condition, to date, we have, from time to time, experienced threats to and breaches of our data and systems, including malware and computer virus attacks. For more information about the cybersecurity risks we face, see the risk factor entitled "Our internal computer systems, or those used by our third-party research institution collaborators, CROs or other contractors or consultants, may fail or suffer security breaches" in Item 1A- Risk Factors.

Governance Related To Cybersecurity Risks

Our cybersecurity process is overseen by our Information Technology department, which is managed by our Head of IT. The Head of IT role is currently held by an individual who has approximately two decades of professional IT management experience. In addition, our Security Leadership Team (SLT), which is comprised of the Head of IT as well as leaders from our operations, finance, and legal departments, is responsible for documenting, reviewing, and assessing our cybersecurity processes, monitoring for cybersecurity incidents, and periodically reporting on cybersecurity risks and risk management to a committee of our executive team (Executive Committee). The Executive Committee, which is led by our Chief Financial Officer, undertakes reviews of our cybersecurity program and assesses any security incident updates from the SLT on a quarterly basis.

The Executive Committee meets with the Audit Committee of our Board of Directors on a quarterly basis to report on and discuss material updates to our cybersecurity program. The Audit Committee provides oversight of our cybersecurity program as part of its periodic review of enterprise risk management and provides regular reports to our Board of Directors regarding our cybersecurity processes, including updates on the status of ongoing cybersecurity projects, the results of cybersecurity risk assessments, and the emerging cybersecurity threat landscape. Additionally, the Board of Directors reviews the enterprise risk management program on at least an annual basis.

ITEM 2. Properties

Facilities

As of December 31, 2022 December 31, 2023, we occupied approximately 200,000 square feet of office, laboratory and Good Manufacturing Practice (GMP) manufacturing space in San Diego, California under a non-cancelable operating lease through May 2036. In addition, we have additional operating leases for office and laboratory space in San Diego, California, San Francisco, California, and New York, New York. California. We believe that these facilities are adequate for our current needs.

ITEM 3. Legal Proceedings

We are currently pursuing claims in two lawsuits that we filed in 2022 against Shoreline Biosciences, Inc. (Shoreline) and certain of its founders and officers (collectively, referred to as the Shoreline litigations). The first suit, filed on May 13, 2022, is pending in San Diego Superior Court against Shoreline and three four of its founders, Drs. Dan S. Kaufman (Kaufman), Kleanthis G. Xanthopoulos, Steven Holtzman, and Steven Holtzman. William Sandborn. Our claims stem from Kaufman's founding of and participation in Shoreline's business, in breach of his exclusivity obligations to us as our scientific advisor pursuant to a Scientific Advisor Agreement between Kaufman and the Company. Our claims include actions for breach of contract, breach of implied covenant of good faith and fair dealing, fraud and deceit, tortious interference, restitution and unfair competition. We Fact and expert discovery is ongoing, and we are seeking monetary damages. Trial is presently scheduled to begin on July 19, 2024.

In the second of the Shoreline litigations, also filed on May 13, 2022, we and Whitehead Institute for Biomedical Research (Whitehead) filed a lawsuit in the U.S. District Court for the Southern District of California against Shoreline and Kaufman seeking monetary damages for the defendants' infringement of U.S. Patent Nos. 8,071,369, 8,932,856, 8,951,797, 8,940,536, 9,169,490, 10,457,917, and 10,017,744 (the Whitehead Patents). The Whitehead Patents, which we exclusively license from Whitehead, relate to key compositions and methods for reprogramming human somatic cells to a pluripotent state in the generation of induced pluripotent stem cells (iPSCs) iPSCs. On June 7,

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2023, we and Whitehead filed a motion to dismiss our patent infringement claims against Kaufman in his personal capacity; that motion was granted on June 9, 2023. On July 14, 2023 each party filed motions for summary judgment. On August 30, 2023, the court granted Shoreline's motion for summary judgment and denied our motion for partial summary judgment as moot. Judgment in favor of Shoreline was entered on August 31, 2023. On October 16, 2023, the district court denied Shoreline's motion for an award of costs and Kaufman have each attorney's fees. On September 27, 2023, we and Whitehead filed answers to our complaint denying infringement a Notice of Appeal with the Court of Appeals for the Federal Circuit challenging the trial court's claim construction and alleging invalidity grant of summary judgment in favor of the Whitehead Patents.

defendants; the defendants cross-appealed challenging the district court's earlier denial of a motion to dismiss and partial motion for summary judgment on other grounds. The Shoreline litigations are in Federal Circuit docketed the discovery stage and remain pending.case on October 5, 2023. There can be no assurance that we will prevail on any such appeal. We filed our opening appeal brief on February 2, 2024.

On January 20, 2023, a purported stockholder of the Company filed a securities class action lawsuit against the Company and certain of its officers captioned Hadian v. Fate Therapeutics, Inc. et al. in the U.S. District Court for the Southern District of California. California (the Securities Action). On May 4, 2023, the court appointed a different purported stockholder of the Company to serve as lead plaintiff in the Securities Action. On July

24, 2023, the lead plaintiff filed an amended complaint. The amended complaint alleges that the Company violated the federal securities laws by making allegedly false and/or misleading statements and/or omissions in its public disclosures dating back to April August 2020 relating to the Company's our collaboration agreement with Janssen Biotech, Inc. (the Janssen Agreement), potential future revenue sources for the Company from product candidates subject to the Janssen Agreement, and the termination of the Janssen Agreement. On September 22, 2023, we filed a motion to dismiss the amended complaint in its entirety. Briefing on our motion to dismiss was completed on December 6, 2023. The court may, in its discretion, either hold oral argument on the motion to dismiss or issue a ruling on the motion based upon the parties' briefing. We believe that there intend to continue to vigorously defend against this action.

On June 2, 2023, a derivative complaint, captioned Guarino v. Wolchko, et al., was filed by a purported stockholder of the Company in the U.S. District Court for the Southern District of California. The derivative lawsuit names members of our board of directors and certain officers as defendants. The Company is no merit named as a nominal defendant. The plaintiff asserts derivative claims arising out of substantially the same alleged facts and circumstances as the Securities Action. The complaint asserts claims for breach of fiduciary duty, unjust enrichment, abuse of control, gross mismanagement, waste of corporate assets, and violation of federal securities laws. On August 14, 2023, the court stayed the derivative lawsuit pending the court's decision on our motion to this case and we dismiss in the Securities Action filed September 22, 2023. We intend to vigorously defend against it. this action.

From time to time, we may be subject to various other legal proceedings and claims that arise in the ordinary course of our business activities.

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

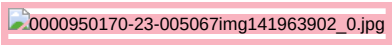
Our ticker symbol is "FATE", as traded and reported by The NASDAQ Global Market.

Holders of Common Stock

As of February 22, 2023 February 20, 2024, there were approximately 22 19 stockholders of record of our common stock. The approximate number of holders is based upon the actual number of holders registered in our records at such date and excludes holders in "street name" or persons, partnerships, associations, corporations, or other entities identified in security positions listings maintained by depository trust companies.

Performance Graph

Set forth below is a graph comparing the cumulative total return on our common stock, the NASDAQ Composite® (US) Index and the NASDAQ Biotechnology Index over the five-year period ending December 31, 2022. The graph assumes that $100 was invested in our common stock and in each of the comparative indices as of the market close on December 31, 2017. The past performance of our common stock is no indication of future performance.



Dividends

We have never declared or paid any dividends on our capital or common 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 will be made at the discretion of our board of directors.

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Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Recent Sales of Unregistered Securities

During the year ended December 31, 2022 December 31, 2023, we did not issue or sell any unregistered securities not previously disclosed in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K.

Issuer Purchases of Equity Securities

We did not repurchase any securities during the year ended December 31, 2022 December 31, 2023.

ITEM 6. [Reserved]

Not applicable.

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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 consolidated financial statements and related notes included under Item 8 of this Annual Report on Form 10-K. The following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those expressed or implied in any forward-looking statements as a result of various factors, including those set forth under the caption "Item 1A. Risk Factors."

This section of this Form 10-K generally discusses 2022 and 2021 items and year-to-year comparisons between 2022 and 2021. Discussions of 2020 items and year-to-year comparisons between 2021 and 2020 that are not included in this Form 10-K can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 as filed with the Securities and Exchange Commission on February 28, 2022 and incorporated herein by reference.

Overview

We are a clinical-stage biopharmaceutical company dedicated to bringing a first-in-class pipeline of programmed cellular immunotherapies to patients with cancer and autoimmune disorders. diseases. Our development of first-in-class cell therapy product candidates programmed cellular immunotherapies is based on a simple notion: we believe that better cell therapies start with better cells.

To create better cell therapies, we have pioneered a therapeutic approach that we generally refer to as cell programming: we create and engineer human induced pluripotent stem cells (iPSCs) to incorporate novel synthetic controls of cell function; we generate a clonal master iPSC line for use as a renewable source of cell manufacture; and we direct the fate of the clonal master iPSC line to produce our first-in-class cell therapy product candidate. Analogous to master cell lines used to manufacture biopharmaceutical drug products such as monoclonal antibodies, we believe clonal master iPSC lines can be used to mass produce multiplexed-engineered cellular immunotherapies which are well-defined and uniform in composition, can be stored in inventory for off-the-shelf availability, can be combined and administered with other therapies, and can have broader patient reach.

Utilizing this therapeutic approach, our proprietary iPSC product platform, we are advancing a cell therapy pipeline comprised of off-the-shelf, multiplexed-engineered iPSC-derived natural killer (NK) and T-cell product candidates that which are selectively designed to incorporate novel synthetic controls of cell function, and are intended to deliver multiple mechanisms of therapeutic importance mechanisms to patients for the treatment of cancer and autoimmune disease.

diseases. We have a deep pipeline of iPSC-derived, chimeric antigen receptor (CAR)-targeted NK and T-cell product candidates currently under development with multiple clinical trials ongoing. In addition, we have entered into a research collaboration collaborations and license agreement agreements with academic institutes to support the development of our iPSC product platform and our off-the-shelf product candidates.

including, among others, the Regents of the University of Minnesota to develop off-the-shelf, engineered NK-cell cancer immunotherapies derived from clonal master iPSC lines. Additionally, we have entered into a research collaboration and license agreement with Memorial Sloan Kettering Cancer Center (MSK) to develop off-the-shelf, engineered T-cell cancer immunotherapies derived from clonal master iPSC lines. (MSKCC).

We have also entered into collaborations with pharmaceutical companies to research, develop and commercialize off-the-shelf, multiplexed-engineered, iPSC-derived NK and T-cell product candidates for the treatment of cancer. In September 2018, we entered into a collaboration and option agreement (Ono Agreement) with Ono Pharmaceutical Co., Ltd. (Ono) for the joint development, under which we are currently researching and commercialization of off-the-shelf, developing iPSC-derived CAR NK and CAR T-cell product candidates (Ono Agreement) for the treatment of cancer. In June 2022, we entered into an amendment (Ono Amendment) to the Ono Agreement to expand the collaboration to include the research and development of off-the-shelf, iPSC-derived CAR NK-cell product candidates and pursuant to the Ono Agreement, Ono agreed to provide novel binding domains targeting a second solid tumor antigen under the collaboration.

tumors. In April 2020, we entered into a collaboration and option agreement (Janssen Agreement) with Janssen Biotech, Inc. (Janssen), part of the Janssen Pharmaceutical Companies of Johnson & Johnson, (Janssen Agreement), for the research, development and commercialization of off-the-shelf, iPSC-derived CAR NK and CAR T-cell product candidates for the treatment of cancer. On January 3, 2023, we received notice of termination from Janssen of the Janssen Agreement. During 2022, Janssen had exercised a commercial option for two collaboration candidates: an iPSC-derived, CAR-targeted NK cell product candidate for the treatment of B-cell lymphoma, for which the U.S. Food and Drug Administration (the FDA) allowed an Investigational New Drug (IND) application in December 2022; and an iPSC-derived, CAR-targeted NK cell product candidate for the treatment of multiple myeloma, for which the companies were preparing to submit an IND application to the FDA in early 2023. In addition, the companies were researching and preclinically developing two iPSC-derived, CAR-targeted T-cell programs for the treatment of solid tumors. The termination of the Janssen Agreement will take from Janssen, which took effect on April 3, 2023 and, during the first quarter of 2023, we will wind down our activities with Janssen, including discontinuing development of all collaboration products.

As a result of the termination of the Janssen collaboration and the NK cell program prioritization, during the first quarter of 2023 we are reducing our workforce to approximately 220 employees. We expect that we will incur charges of approximately $12 million to $16 million for severance and other employee termination-related costs in the first quarter of 2023. The restructuring is expected to extend our cash runway into the second half of 2025. .

We were incorporated in Delaware in 2007 and are headquartered in San Diego, CA. California. Since our inception in 2007, we have devoted substantially all of our resources to our cell programming approach and the research and development of our product

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candidates, the creation, licensing and protection of related intellectual property, and the provision of general and administrative support for these activities. To date, we have funded our operations primarily through the public and private sale of common stock, the private placement of preferred stock and convertible notes, commercial bank debt and revenues from collaboration activities and grants.

We have never been profitable and have incurred net losses in each year since inception. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur operating losses for at least the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. We expect our expenses will increase substantially remain significant in connection with our ongoing and planned activities as we:

- conduct our ongoing and planned preclinical studies and clinical trials of our product candidates, which may include higher clinical trial expenses associated with arrangements we may enter into with clinical research organizations (CROs) for the execution and management of certain clinical trials, including trials outside of the United States;
- conduct Good Manufacturing Practice (GMP) production, including through the use of contract manufacturing organizations (CMOs) for the conduct of some or all of the activities required for manufacturing our iPSC-derived cell product candidates, process and scale-up development and technology transfer activities for the manufacture of our product candidates, including those undergoing clinical investigation and IND-enabling IND application-enabling preclinical development;

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- procure laboratory equipment, materials and supplies for the manufacture of our product candidates and the conduct of our research activities;
- conduct preclinical and clinical research to investigate the therapeutic activity of our product candidates;
- continue our research, development and manufacturing activities, including under our sponsored research and collaboration agreement with Ono:

- maintain, prosecute, protect, expand and enforce our intellectual property portfolio;
- engage with regulatory authorities for the development of, and seek regulatory approvals for, our product candidates;
- build out continue our business operations at our corporate headquarters, including maintaining internal GMP production capabilities;
- continue to implement the corporate restructuring and reduction in force that we announced in January 2023; and
- continue operating as a public company and support our operations and develop commercial infrastructure for potential commercialization of our product candidates. operations.

We do not expect to generate any meaningful revenues from product sales, royalties, or sales milestones unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will seek to fund our operations through public or private equity or debt financings, collaboration arrangements, or other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative effect on our financial condition and ability to develop our product candidates.

Due to the global outbreak of SARS-CoV-2, the strain of coronavirus that causes Coronavirus disease 2019 (COVID-19), we continued to experience impacts on certain aspects of our business, including our clinical trial, manufacturing, and research and development activities, during the year ended December 31, 2022. For example, we also continue to experience delays in obtaining equipment, materials, and supplies needed to conduct our clinical trials, maintain our operations, and manufacture our product candidates as a result of production shortages experienced by our suppliers in connection with the COVID-19 pandemic. The scope and duration of these delays and disruptions, and the ultimate impacts of the COVID-19 pandemic on our operations, remain uncertain, and depend on continuously changing circumstances, including the emergence of new variants of the virus. We continue to monitor the impact of the COVID-19 pandemic on our business and may take further precautionary and preemptive actions as may be required by federal, state or local authorities or that we determine are in the best interests of public health and safety and that of our patient community, employees, partners, and stockholders. For more information regarding the risks and uncertainties associated with the evolving effects of COVID-19 on our business, our preclinical and clinical development and regulatory efforts, refer to Part I Item 1A. Risk Factors.

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Financial Operations Overview

We conduct substantially all of our activities through Fate Therapeutics, Inc., a Delaware corporation, at our facilities headquartered in San Diego, California. The results of operations include the operations of the Company and its subsidiaries. To date, the aggregate operations of our subsidiaries have not been significant and all intercompany transactions and balances have been eliminated in consolidation.

Collaboration Revenue

To date, we have not generated any revenues from therapeutic product sales or royalties. Our revenues have been derived from collaboration agreements and government grants.

Agreement with Janssen Biotech, Inc.

On April 2, 2020 (the Janssen Agreement Effective Date), we entered into a Collaboration and Option Agreement (the Janssen Agreement) with Janssen Biotech, Inc. (Janssen), part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Additionally, on the Janssen Agreement Effective Date, we entered into a Stock Purchase Agreement (the Stock Purchase Agreement) with Johnson & Johnson Innovation - JJDC, Inc. (JJDC). Under the terms of the Janssen Agreement and the Stock Purchase Agreement taken together, we received $100.0 million, of which $50.0 million was an upfront cash payment and $50.0 million was in the form of an equity investment by JJDC. Additionally, we are entitled to receive fees for the conduct of all research, preclinical development and IND-enabling activities performed by us under the Janssen Agreement.

We determined the common stock purchase by JJDC represented a premium of $9.93 per share, or $16.0 million in aggregate (the Equity Premium), and the remaining $34.0 million was recorded as issuance of common stock in shareholders' equity.

We concluded that certain units of account within the Janssen Agreement represented a customer relationship, and in accordance with Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* (ASC 606), we determined that the initial transaction price under the Janssen Agreement equals $66.0 million, consisting of the upfront, non-refundable and non-creditable payment of $50.0 million and the Equity Premium of $16.0 million. In addition, we identified our potential performance obligations under the Janssen Agreement, including our grant to Janssen of a license to certain of our intellectual property subject to certain conditions, our conduct of research and development services, and our participation in various joint oversight committees. We determined that our grant of a license to Janssen and our conduct of research and development services

in various joint oversight committees. We determined that our grant of a license to Janssen and our conduct of research and development services should be accounted for as one combined performance obligation, and that the combined performance obligation is transferred over the expected term of the conduct of the research and development services, which is estimated to be four years. Additionally, we determined that participation in the various joint oversight committees did not constitute a performance obligation as our participation in the various joint oversight committees does not transfer a service.

During the year ended December 31, 2022, we achieved two pre-defined research milestones under the Janssen Agreement and received a cash payment of $3.0 million per milestone achieved, for a total of $6.0 million received.

During the year ended December 31, 2022, Janssen elected to exercise a commercial option for two separate development candidates with respect to two particular Janssen Antigens (as defined under the Janssen Agreement), and as a result, we received one of the Option Exercise Payments (as defined under the Janssen Agreement) of $10.0 million cash, and are entitled to receive an additional Option Exercise Payment (as defined under the Janssen Agreement) of $10.0 million.

During the year ended December 31, 2022, we filed an IND for the second antigen, development candidate, which was cleared by the FDA on December 15, 2022. Accordingly, we achieved a pre-defined clinical development milestone under the Janssen Agreement and are entitled to receive a $3.0 million payment from Janssen.

During the year ended December 31, 2022, we recognized $79.7 million of collaboration revenue under the Janssen Agreement. During the year ended December 31, 2021, we recognized $43.7 million of collaboration revenue under the Janssen Agreement. As of December 31, 2022, aggregate deferred revenue related to the Janssen Agreement was $41.2 million.

On January 3, 2023, we received notice of termination from Janssen of the Janssen Agreement. The termination will take effect on April 3, 2023 and, during the first quarter of 2023, we will wind down our activities with Janssen, including discontinuing development of all collaboration products. Under the terms of the Janssen Agreement, in connection with the termination, (i) all licenses and other rights granted to either party pursuant to the Janssen Agreement will terminate, subject to limited exceptions set forth in the Janssen Agreement; (ii) both parties will wind down any development, commercialization and manufacturing activities under the Janssen Agreement; (iii) neither party will have any right to continue to develop, manufacture or commercialize any collaboration candidate or collaboration product or use the other party's materials; and (iv) neither party is restricted from independently developing, manufacturing, or commercializing any product, including any products directed to the same antigens as those of any collaboration candidate or collaboration product. We expect to recognize the remaining amount of deferred revenue of

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$41.2 million and any payments from Janssen for wind down activities, which cannot currently be estimated, during the first quarter of 2023.

Agreement with Ono Pharmaceutical Co., Ltd.

On September 14, 2018, we entered into a Collaboration and Option the Ono Agreement (the Ono Agreement) with Ono for the joint development and commercialization of two off-the-shelf iPSC-derived CAR T-cell product candidates (Candidate 1 and Candidate 2). Pursuant to the terms of the Ono Agreement, we received an upfront, non-refundable and non-creditable payment of $10.0 million. Additionally, we are entitled to receive fees for the conduct of research and development under a joint development plan, which fees were estimated to be $20.0 million in aggregate.

We concluded that certain units of account within the Ono Agreement represented a customer relationship and in accordance with ASC 606, we determined that the initial transaction price under the Ono Agreement equals $30.0 million, consisting of the upfront, non-refundable and non-creditable payment of $10.0 million and the aggregate estimated research and development fees of $20.0 million. In addition, we identified our performance obligations under the Ono Agreement, including our grant to Ono of a license to certain of our intellectual property subject to certain conditions, our conduct of research services, and our participation in a joint steering committee. We determined that all performance obligations should be accounted for as one combined performance obligation since no individual performance obligation is distinct, and that the combined performance obligation is transferred over the expected term of the conduct of the research services, which is estimated to be four years.

In December 2020, we entered into a letter agreement with Ono pursuant to which Ono delivered proprietary antigen binding domains targeting an antigen expressed on certain solid tumors for incorporation into Candidate 2 and paid the Company a milestone fee of $10.0 million for further research and development of Candidate 2. In addition, Ono terminated all further research and development with respect to Candidate 1, and we retained all rights to research, develop and commercialize Candidate 1 throughout the world without any obligation to Ono.

In June 2022, we entered into an amendment with the 2022 Ono Amendment. Pursuant to the Ono Agreement (the Ono Amendment). Pursuant to the 2022 Ono Amendment, the companies agreed to designate an additional antigen expressed on certain solid tumors for research and preclinical development, and Ono agreed to contribute proprietary antigen binding domains targeting such additional solid tumor antigen (Candidate 3). In addition, for both Candidate 2 and Candidate 3, the companies expanded the scope of the collaboration to include the research and development of iPSC-derived CAR NK cell product candidates (in addition to iPSC-derived CAR T-cell product candidates) targeting the designated solid tumor antigens. Similar to Candidate 2, we granted to Ono, during a specified period of time, a preclinical option to obtain an exclusive license under certain intellectual property rights, subject to payment of an option exercise fee to us by Ono, to develop and commercialize Candidate 3 in all territories of the world,

where we retain rights to co-develop and co-commercialize Candidate 3 in the United States and Europe under a joint arrangement with Ono under which we are eligible to share at least 50% of the profits and losses. We maintained worldwide rights of manufacture for Candidate 3. The preclinical option expires upon the earlier of: (a) September 30, 2024, or (b) the achievement of the pre-defined preclinical milestone under the joint development plan for Candidate 3. Subject to payment of an extension fee by Ono, Ono may choose to defer its decision to exercise the preclinical option until no later than June 2026. Under the 2022 Ono Amendment, aggregate estimated research and development fees have been increased by approximately $9.3 million, for a total estimated $29.3 million in aggregate research and development fees over the course of the joint development plan.

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In November 2022, Ono exercised its preclinical option to Candidate 2, and we exercised our preclinical option to co-develop and co-commercialize (CDCC Option) in the United States and Europe under a joint arrangement with Ono. As a result, we are entitled to recognized an option exercise fee of $12.5 million from Ono. Ono during the year ended December 31, 2022. We received the option exercise fee payment during the year ended December 31, 2023.

On November 30, 2023, we entered into the 2023 Ono Amendment. Under the 2023 Ono Amendment, aggregate estimated research and development fees have been increased by approximately $1.4 million, for a total estimated $30.7 million in aggregate research and development fees over the course of the joint development plan.

We account for the Ono Agreement as a revenue contract under ASC 606. The initial transaction price as amended under the 2023 Ono Amendment was determined to be $40.7 million, consisting of the upfront, non-refundable and non-creditable payment of $10.0 million and the aggregate estimated research and development fees of $30.7 million. We identified our promised goods and services under the Ono Agreement to include our grant to Ono of a license to certain of our intellectual property subject to certain conditions, our conduct of research services, and our participation in a joint steering committee. We determined that the promised goods and services should be accounted for as one combined performance obligation. We recognize revenue for the combined performance obligation over time as the research services are performed.

During the years ended December 31, 2022 December 31, 2023 and 2021, 2022, we recognized $16.6 million $11.2 million and $12.1 million $16.6 million, respectively, of collaboration revenue under the Ono Agreement. As of December 31, 2022 December 31, 2023, aggregate deferred revenue related to the Ono Agreement, and Ono Letter Agreement, and Ono Amendments was $1.1 million $0.7 million.

Agreement with Janssen Biotech, Inc.

On April 2, 2020, we entered into the Janssen Agreement as well as a Stock Purchase Agreement (the Stock Purchase Agreement) with Johnson & Johnson Innovation - JJDC, Inc. (JJDC). On January 3, 2023, we received notice of termination from Janssen of the Janssen Agreement. The termination took effect on April 3, 2023, and during the three months ending March 31, 2023, we performed wind down activities, including discontinuing development of all collaboration product candidates under the Janssen Agreement. We were reimbursed for all wind down activities associated with the termination of the Janssen Agreement during the second quarter of this year.

Under the terms of the Janssen Agreement and the Stock Purchase Agreement taken together, we received $100.0 million, of which $50.0 million was an upfront cash payment and $50.0 million was in the form of an equity investment by JJDC. We determined the common stock purchase by JJDC represented a premium of $9.93 per share, or $16.0 million in aggregate (the Equity Premium), and the remaining $34.0 million was recorded as issuance of common stock in shareholders' equity.

Additionally, prior to termination of the Janssen Agreement, we received fees from Janssen for the conduct of all research, preclinical development and IND-enabling activities performed by us under the Janssen Agreement. In addition, Janssen had exercised a commercial option for two collaboration candidates: an iPSC-derived, CAR NK cell product candidate for the treatment of B-cell lymphoma, for which the U.S. Food and Drug Administration (FDA) allowed an Investigational New Drug (IND) application in December 2022; and an iPSC-derived, CAR NK cell product candidate for the treatment of multiple myeloma, for which the companies were preparing to submit an IND application to the FDA in early 2023.

Research and Development Expenses

Research and development expenses consist of costs associated with the research, preclinical development, process and scale-up development, manufacture and clinical development of our product candidates, the research and development of our cell programming technology including our iPSC product platform, and the performance of research and development activities under our collaboration agreements. These costs are expensed as incurred and include:

- salaries and employee-related costs, including stock-based compensation;
- costs incurred under clinical trial agreements with investigative sites;

- costs incurred under clinical trial agreements with investigative sites;
- costs to acquire, develop and manufacture preclinical study and clinical trial materials, including our product candidates;

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- costs associated with conducting our preclinical, process and scale-up development, manufacturing, clinical and regulatory activities, including fees paid to third-party professional consultants, service providers and suppliers;
- costs incurred for our research, development and manufacturing activities, including under our collaboration agreements;
- costs for laboratory equipment, materials and supplies for the manufacture of our product candidates and the conduct of our research activities;
- costs incurred to license and maintain intellectual property; and

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- facilities, depreciation and other expenses including allocated expenses for rent and maintenance of facilities.

We plan to increase continue to significantly invest in our current level of research and development expenses activities for the foreseeable future as we continue the clinical and preclinical development and the manufacture of our product candidates, research and develop our iPSC product platform, and perform our obligations under collaboration agreements including under our agreements with Ono, University of Minnesota and MSK. MSKCC. Our current planned research and development activities over the next twelve months consist primarily of the following:

- conducting clinical trials of our product candidates, including through the engagement of CROs to manage various aspects of our clinical trials;
- conducting GMP production, including through the use of CMOs for the conduct of some or all of the activities required for manufacturing our iPSC-derived cell product candidates, process and scale-up development and technology transfer activities for the manufacture of our product candidates, including those undergoing clinical investigation and IND-enabling preclinical development;
- procuring laboratory equipment, materials and supplies for the manufacture of our product candidates and the conduct of our research activities;
- conducting preclinical and clinical research to investigate the therapeutic activity of our product candidates; and
- conducting research, development and manufacturing activities, including under our sponsored research and collaboration agreement with Ono.

Due to the inherently unpredictable nature of preclinical and clinical development and manufacture, and given our novel therapeutic approach and the current stage of development of our product candidates, we cannot determine and are unable to estimate with certainty the timelines we will require and the costs we will incur for the development and manufacture of our product candidates. Clinical and preclinical development and manufacturing timelines and costs, and the potential of development and manufacturing success, can differ materially from expectations. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development and manufacturing plans and capital requirements. We cannot predict the effects of the impact of global economic and market conditions, a continued and prolonged public health emergency such as the ongoing COVID-19 pandemic, and wars and other armed conflicts, such as the ongoing conflict in wars between Russia and Ukraine and between Israel and Hamas, on our business and operations, and our expenditures may be increased by delays or disruptions due to these or other factors, including as a result of actions we take in the near term to ensure business continuity and protect against possible supply chain shortages.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and employee-related costs, including stock-based compensation, for our employees in executive, operational, finance and human resource functions; professional fees for accounting, legal and tax services; costs for obtaining, prosecuting, maintaining, and enforcing our intellectual property; and other costs and fees, including director and officer insurance premiums, to support our operations as a public company. We anticipate that our general and administrative expenses will increase remain significant in the future as we increase maintain our focus on innovation, and research and development activities, maintain compliance with exchange listing and SEC requirements, protect and enforce our intellectual property, and continue to operate as a public company.

Other Income (Expense)

Other income (expense) consists of changes in the fair value of stock price appreciation milestones associated with the Amended and Restated Exclusive License Agreement dated May 15, 2018 (the Amended MSK (Amended MSKCC License) with Memorial Sloan Kettering Cancer Center (MSK), MSKCC, interest income earned on cash and cash equivalents and interest income from investments (including the amortization of discounts and premiums).

California Institute for Regenerative Medicine Award

80 On April 5, 2018, we executed an award agreement with the California Institute for Regenerative Medicine (CIRM) pursuant to which CIRM awarded us $4.0 million to advance our FT516 product candidate into a first-in-human clinical trial (the Award). In November 2019, we submitted an IND application for FT516 in advanced solid tumors.

Pursuant to the terms of the Award, we, in our sole discretion, have the option to treat the Award either as a loan or as a grant. During the first quarter of 2023, we elected to treat the Award as a grant and derecognized the liability associated with the Award and recorded such amount in other income during the year ended December 31, 2023.

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Employee Retention Credit

The Coronavirus Aid, Relief and Economic Security (CARES) Act provides an employee retention credit (ERC), which is a refundable tax credit against certain employment taxes of up to $5,000 per employee for eligible employers. The tax credit is equal to 50% of qualified wages paid to employees during a quarter, capped at $10,000 of qualified wages per employee through December 31, 2020. Additional relief provisions were passed by the United States government, which extend and slightly expand the qualified wage caps on these credits through December 31, 2021. Based on these additional provisions, the tax credit is now equal to 70% of qualified wages paid to employees during a quarter, and the limit on qualified wages per employee has been increased to $10,000 of qualified wages per quarter. In connection with the CARES Act, we adopted a policy to recognize an ERC when it is reasonably assumed we will comply with the conditions and the grant will be received and include in other income in the statement of operations. The Company received a cash payment and recorded $5.1 million and $0.5 million of other income during the years ended December 31, 2023 and 2022, respectively.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. United States generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to the fair value of the stock price appreciation milestones for the Amended MSK MSKCC License, contracts containing leases, accrued expenses, stock-based compensation, and the estimated total costs expected to be incurred under our collaboration agreements. We base our estimates on historical experience, known trends and events, financial models, and various other factors that are believed to be 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. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe that the following critical accounting policies reflect the more significant procedures, estimates and assumptions used in the preparation of our consolidated financial statements.

Collaborative Arrangements

We analyze our collaboration arrangements to assess whether they are within the scope of ASC Topic 808, *Collaborative Arrangements* ("ASC 808") (ASC 808), to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards that are dependent on the commercial success of such activities. To the extent the arrangement is within the scope of ASC 808, we assess whether aspects of the arrangement with between us and our collaboration partners partner are within the scope of other accounting literature, including ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606") (ASC 606). If it is concluded that some or all aspects of the arrangement represent a transaction with a customer, we will account for those aspects of the arrangement within the scope of ASC 606.

ASC 808 provides guidance for the presentation and disclosure of transactions in collaborative arrangements, but it does not provide recognition or measurement guidance. Therefore, if we conclude a counterparty to a transaction is not a customer or otherwise not within the scope of ASC 606, we

considers consider the guidance in other accounting literature as applicable or by analogy to account for such transaction. The classification of transactions under our arrangements is determined based on the nature and contractual terms of the arrangement along with the nature of the operations of the participants.

Revenue Recognition

We recognize revenue in a manner that depicts the transfer of control of a product or a service to a customer and reflects the amount of the consideration we are entitled to receive in exchange for such product or service. In doing so, we follow a five-step approach: (i) identify the contract with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations, and (v) recognize revenue when (or as) the customer obtains control of the product or service. We consider the terms of a contract and all relevant facts and circumstances when applying the revenue recognition standard. We apply the revenue recognition standard, including the use of any practical expedients, consistently to contracts with similar characteristics and in similar circumstances.

A customer is a party that has entered into a contract with us, where the purpose of the contract is to obtain a product or a service that is an output of our ordinary activities in exchange for consideration. To be considered a contract, (i) the contract must be approved (in writing, orally, or in accordance with other customary business practices), (ii) each party's rights regarding the product or the service to be transferred can be identified, (iii) the payment terms for the product or the service to be transferred can be identified, (iv) the contract must have commercial substance (that is, the risk, timing or amount of future cash flows is expected to change as a result of the contract), and (v) it is probable that we will collect substantially all of the consideration to which we are entitled to receive in exchange for the transfer of the product or the service.

A performance obligation is defined as a promise to transfer a product or a service to a customer. We identify each promise to transfer a product or a service (or a bundle of products or services, or a series of products and services that are substantially the same and have the same pattern of transfer) that is distinct. A product or a service is distinct if both (i) the customer can benefit from the product or the service either on its own or together with other resources that are readily available to the customer and (ii) our promise to transfer the product or the service to the customer is separately identifiable from other promises in the contract. Each distinct promise to transfer a product or a service is a unit of accounting for revenue recognition. If a promise to transfer a product or a service is not separately identifiable from other promises in the contract, such promises should be combined into a single performance obligation. We determined that the promised goods and services for our collaboration agreements should be accounted

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for as one combined performance obligation. We recognize revenue for the combined performance obligation over time as the research services are performed.

The transaction price is the amount of consideration we are entitled to receive in exchange for the transfer of control of a product or a service to a customer. To determine the transaction price, we consider the existence of any significant financing component, the effects of any variable elements, noncash considerations and consideration payable to the customer. If a significant financing component exists, For our collaboration agreements, we calculate the transaction price is adjusted for the time value of money. If as an element of variability exists, we must estimate the consideration we expect to receive and use that amount as the basis for recognizing revenue as the product or the service is transferred to the customer. There are two methods for determining the amount of variable consideration: (i) the expected value method, which is the sum of probability-weighted amounts in a range of possible consideration amounts, and (ii) the mostly likely amount method, which identifies the single most likely amount in a range of possible consideration amounts.

If a contract has multiple performance obligations, we allocate the transaction price to each distinct performance obligation in an amount that reflects the consideration we are entitled to receive in exchange for satisfying each distinct performance obligation. For each distinct performance obligation, revenue is recognized when (or as) we transfer control of the product or the service applicable to such performance obligation.

In those instances where we first receive consideration in advance of satisfying its performance obligation, we classify such consideration as deferred revenue until (or as) we satisfy such performance obligation. In those instances where we first satisfy our performance obligation prior to our receipt of consideration, the consideration is recorded as accounts receivable.total research and development plan reimbursement.

We expense incremental costs of obtaining and fulfilling a contract as and when incurred if the expected amortization period of the asset that would be recognized is one year or less, or if the amount of the asset is immaterial. Otherwise, such costs are capitalized as contract assets if they are incremental to the contract and amortized to expense proportionate to revenue recognition of the underlying contract.

Stock Price Appreciation Milestones

We estimate the fair value of the stock price appreciation milestones under the Amended MSK MSKCC License using a Monte Carlo simulation model, which relies on our current stock price at the end of each quarter as well as significant estimates and assumptions to determine the estimated liability associated with the contingent milestone payments. We account for the fair value of the stock price appreciation milestones in accordance with ASC 815, *Derivatives and Hedging*, with fair value marked to market. The assumptions used to calculate the fair value of the stock price appreciation milestones are subject to a significant amount of judgment including the assessment of achieving a specified clinical milestone, the expected volatility of our common stock, the risk-free interest rate and the estimated term, which is based in part on the last valid patent claim date. We achieved the specified clinical milestone in July 2021 and met the first milestone during fiscal 2021. Accordingly, we remitted a payment to MSK MSKCC of $20.0 million in the year ended December 31, 2021. We remeasure the fair value of the remaining stock price appreciation milestones at each balance sheet date, with changes in fair value recorded in earnings as a non-operating income or expense.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of accrued research and development expenses include amounts owed to clinical research organizations, to investigative sites in connection with clinical trials, to sponsored research organizations, to service providers in connection with preclinical development activities and to service providers related to product manufacturing, development and distribution of clinical supplies.

We base our accrued expenses related to clinical trials on our estimates of the services performed and efforts expended pursuant to our contractual arrangements, including those with clinical research organizations. The financial terms of these agreements are sometimes subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our service providers will exceed the level of services performed and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical milestones. 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 prepaid accordingly.

Although we do not expect our estimates to be materially different from expenses actually incurred, if our estimates of the status and timing of services performed differs from the actual status and timing of services performed, we may report amounts that are too

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high or too low in any particular period. To date, there have been no material differences from our estimates to the amounts actually incurred.

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Stock-Based Compensation

Stock-based compensation expense represents the grant date fair value of employee stock option and restricted stock unit grants recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis. Performance-based stock units/awards represent a right to receive a certain number of shares of common stock based on the achievement of corporate performance goals and continued employment during the vesting period. At each reporting period, and to the extent achievement of one or any of the performance conditions is probable, we reassess the probability of the achievement of such corporate performance goals and any increase or decrease in share-based compensation expense resulting from an adjustment in the estimated shares to be released is treated as a cumulative catch-up in the period of adjustment.

We estimate the fair value of stock option grants using the Black-Scholes option pricing model, with the exception of option grants with both performance-based milestones and market conditions, which are valued using a lattice-based model. These models require the use of highly subjective and complex assumptions which determine the fair value of stock-based awards, (a) the risk-free interest rate, (b) the expected volatility of our stock, (c) the expected term of the award and (d) the expected dividend yield. The expected volatility is based on the historical volatility of our common stock over

the expected term of the award and (d) the expected dividend yield. The expected volatility is based on the historical volatility of our common stock over the most recent period commensurate with the estimated expected term of our stock options which is derived from historical experience and anticipated future exercise behavior. The risk-free interest rates for periods within the expected life of the option are based on the yields of zero-coupon U.S. Treasury securities. See Note 9 of the notes to the consolidated financial statements for additional information.

The fair value of our restricted stock units, including performance-based restricted stock units, is based on the closing price of our common stock as reported on The NASDAQ Global Market on the date of grant.

Recent Accounting Pronouncements

For a discussion of recently issued accounting pronouncements, please see Note 1 of the notes to the consolidated financial statements.

Results of Operations

Comparison of Years Ended December 31, 2022 December 31, 2023 and 2021 2022

The following table summarizes the results of our operations for the years ended December 31, 2022 December 31, 2023 and 2021: 2022:

	Years Ended December 31,		Increase/ (Decrease)	Years Ended December 31,		Increase/ (Decrease)
	2022	2021		2023	2022	
	(in thousands)			(in thousands)		
Collaboration revenue	$ 96,300	$ 55,846	$ 40,454	$ 63,533	$ 96,300	$ (32,767)
Research and development expenses	320,454	215,519	104,935	172,596	320,454	(147,858)
General and administrative expenses	84,232	57,321	26,911	81,448	84,232	(2,784)
Total other income, net	26,665	4,843	21,822	29,583	26,665	2,918

Revenue. During the year ended December 31, 2023, we recognized revenue of $63.5 million under our collaboration agreements with Janssen and Ono. During the year ended December 31, 2022, we recognized revenue of $96.3 million under our collaboration agreements with Janssen and Ono. During The decrease in revenue was attributable primarily to the year ended December 31, 2021, we recognized revenue termination of $55.8 million under our collaboration agreements with Janssen in April 2023. The following table summarizes the revenue recognized with respect to each collaboration partner for the years ended December 31, 2023 and Ono.2022:

	Years Ended December 31,	
	2023	2022
	(in thousands)	
Janssen Biotech, Inc.	$ 52,312	$ 79,662
Ono Pharmaceutical Co., Ltd.	11,221	16,638
Total collaboration revenue	$ 63,533	$ 96,300

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Research and development expenses. Research and development expenses were $172.6 million for the year ended December 31, 2023, compared to $320.5 million for the year ended December 31, 2022, compared to $215.5 million for the year ended December 31, 2021. The increase decrease in research and development expenses includes the impact of the termination of our collaboration with Janssen in April 2023 and was attributable primarily to the following:

- $38.3 63.6 million increase decrease in employee compensation and benefits expense, which includes a $16.0 million increase $30.3 million decrease in employee-stock based compensation expense;
- $31.3 48.4 million increase in third-party professional consultant and clinical trial related expense; and
- $17.6 million increase decrease in expenditures for laboratory materials and supplies relating to the manufacture of our product candidates and the conduct of our research activities, including under our collaboration agreements. agreements; and
- $29.0 million decrease in third-party professional consultant and clinical trial related expense

General and administrative expenses. General and administrative expenses were $81.4 million for the year ended December 31, 2023, compared to $84.2 million for the year ended December 31, 2022, compared to $57.3 million for the year ended December 31, 2021. The increase decrease in general and administrative expenses was attributable primarily to the following:

- $14.5 10.6 million increase decrease in employee compensation and benefits expense, which includes a $8.4 million increase $5.0 million decrease in employee stock-based compensation expense;
- $5.9 1.8 million decrease in office and computer supplies; and
- $10.6 million increase in patent and legal expense; and
- $1.0 million increase in maintenance related expenses. expense.

Other income (expense), net. income. Other income (expense), net was $26.7 million $29.6 million and $4.8 million $26.7 million for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively. During the year ended December 31, 2022 December 31, 2023, we recorded $20.3 million $4.0 million in income attributable to the CIRM Award, $5.1 million in income attributable to the ERC, and $2.5 million in other income attributable to the change in fair value of the stock price appreciation milestone under the Amended MSK MSKCC License. Other income (expense) for the year ended December 31, 2023 also consisted of $17.2 million interest income earned on cash and cash equivalents and interest income from investments (including the amortization of discounts and premiums). During the year ended December 31, 2022, net we recorded $20.3 million in other income attributable to the fair value of the stock price appreciation milestones under the Amended MSKCC License. Other income for the year ended December 31, 2022 also consisted of interest income earned on cash and cash equivalents and interest income from investments (including the amortization of discounts and premiums). During the year ended December 31, 2021, we recorded $3.5 million in other expense attributable to the fair value of the stock price appreciation milestones under the Amended MSK License. Other income (expense), net for the year ended December 31, 2021 also consisted of interest income earned on cash and cash equivalents and interest income from investments (including the amortization of discounts and premiums).

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations since inception. As of December 31, 2022 December 31, 2023, we had an accumulated deficit of $1.05 billion $1.2 billion and anticipate that we will continue to incur net losses for the foreseeable future.

The following table sets forth a summary of the net cash flow activity for each of the years ended December 31:

	2022	2021	2023	2022
	(in thousands)		(in thousands)	
Net cash used in operating activities	$ (248,208)	$ (162,870)	$ (132,263)	$ (248,208)
Net cash used in investing activities	166,751	(324,023)		
Net cash provided by investing activities			112,665	166,751
Net cash provided by financing activities	9,207	453,129	85	9,207
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (72,250)	$ (33,764)	$ (19,513)	$ (72,250)

Operating Activities

Cash used in operating activities increased decreased from $162.9 million for the year ended December 31, 2021 to $248.2 million for the year ended December 31, 2022 to $132.3 million for the year ended December 31, 2023. The primary drivers of this change in cash used in operating activities was our increase decrease of $69.6 million $120.8 million in net loss.

Agreement with Janssen Biotech, Inc.

On April 2, 2020 (the Janssen Agreement Effective Date), we entered into loss primarily due to the Janssen Agreement with Janssen to develop iPSC-derived CAR NK- and CAR T-cell product candidates for the treatment of cancer. Additionally, on the Janssen Agreement Effective Date, we entered into the Stock Purchase Agreement with JJDC. Under the terms termination of the Janssen Agreement agreement, restructuring activities and the Stock Purchase Agreement taken together, we received $100.0 million as discontinuation of the Janssen Agreement Effective Date, of which $50.0 million was an upfront cash payment and $50.0 million was programs implemented in the form of an equity investment by JJDC. Of the $50.0 million equity investment, $16.0 million represented a premium over the fair value of our common stock and was classified under operating activities.

We were entitled to receive fees for the conduct of all research, preclinical development and IND-enabling activities performed by us under the Janssen Agreement. Additionally, we were eligible to receive (i) with respect to the first Janssen Cancer Target, payments of up to $898.0 million upon the achievement of specified development, regulatory and sales milestones (the Janssen Milestone Payments) for the first Collaboration Candidate, and up to $460.0 million in Janssen Milestone Payments for each additional Collaboration Candidate, directed to the first Janssen Cancer Target; and (ii) with respect to each of the second, third and fourth Janssen Cancer Targets, payments of up to $706.0 million in Janssen Milestone Payments for each

of the first Collaboration Candidates, and up to $340.0 million in Janssen Milestone Payments for each additional Collaboration Candidate, directed to the applicable Janssen Cancer Target, where certain Janssen Milestone Payments are subject to reduction in the event we elect to co-commercialize and share equally in the profits and losses in the United States of a respective Collaboration Candidate. We were further eligible to receive double-digit tiered royalties ranging up to the mid-teens on net sales of Collaboration Candidates commercialized by Janssen under the Janssen Agreement, subject to reduction under certain circumstances.

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During the year ended December 31, 2022, we achieved two pre-defined research milestones under the Janssen Agreement and received a cash payment of $3.0 million per milestone, for a total of $6.0 million. During the year ended December 31, 2022, Janssen elected to exercise two commercial options for two development candidates, and we received one of the Option Exercise Payments of $10.0 million during the year. Additionally, during the year ended December 31, 2022, we filed an IND for the second antigen, development candidate, which was cleared by the FDA on December 15, 2022. Accordingly, we achieved a pre-defined clinical development milestone under the Janssen Agreement and are entitled to receive a $3.0 million payment from Janssen. As of December 31, 2022, no royalties have been paid to us under the Janssen Agreement.

In connection with the Janssen Agreement, we have incurred $17.1 million in sublicense fees to certain of our existing licensors, of which $15.6 million has been paid as of December 31, 2022. The $17.1 million in sublicense consideration represents an asset under ASC 340, *Other Assets and Deferred Costs* and is amortized to research and development expense ratably with our revenue recognition under the Janssen Agreement.

Agreement with Ono Pharmaceutical Co., Ltd.

On September 14, 2018, we entered into the Ono Agreement with Ono for the joint development and commercialization of two off-the-shelf, iPSC-derived CAR T-cell product candidates (each a Candidate and collectively the Candidates). Under the terms of the Ono Agreement, Ono paid to us an upfront, non-refundable and non-creditable payment of $10.0 million. Additionally, as consideration for our conduct of research and preclinical development under a joint development plan, Ono pays us annual research and development fees set forth in the annual budget included in the joint development plan, which fees are estimated to be $20.0 million in aggregate over the course of the joint development plan. Further, under the terms of the Ono Agreement, Ono had agreed to pay us up to an additional $40.0 million, subject to the achievement of a preclinical milestone and the exercise by Ono of its options to obtain exclusive licenses to develop and commercialize the Candidates. Such fees are in addition to the upfront payment and research and development fees.

On December 4, 2020, we entered into the Ono Letter Agreement with Ono in connection with the Ono Agreement. Pursuant to the Ono Letter Agreement, Ono delivered to us proprietary antigen binding domains targeting an antigen expressed on certain solid tumors and nominated such antigen binding domains as the Ono Antigen Binding Domain for incorporation into Candidate 2. In connection with such nomination, Ono paid us a milestone fee of $10.0 million in December 2020 for further research and development of Candidate 2 under the Ono Agreement, and Ono continues to maintain its option to Candidate 2 under the Ono Agreement. In addition, the Ono Letter Agreement terminated further development with respect to Candidate 1.

On June 28, 2022, we entered into the Ono Amendment, which expanded the scope of the collaboration to include the research and development of CAR-targeted NK cells, and pursuant to which Ono agreed to contribute novel binding domains targeting a second solid tumor antigen (Candidate 3). Under the Ono Amendment, aggregate estimated research and development fees have been increased by approximately $9.3 million, for a total estimated $29.3 million in aggregate research and development fees over the course of the joint development plan, subject to Ono exercising its option to continue the research term for a candidate targeting the second solid tumor antigen.

Pursuant to the Ono Amendment, we and Ono are jointly conducting research and development activities under a joint development plan, with the goal of advancing Candidate 2 and Candidate 3 to a pre-defined preclinical milestone. We have granted to Ono, during a specified period of time, an option to obtain an exclusive license under certain intellectual property rights to develop and commercialize each remaining candidate in all territories of the world, with us retaining the right to co-develop and co-commercialize in the United States and Europe under a joint arrangement whereby we are eligible to share at least 50% of the profits and losses (the Option).

On November 7, 2022, Ono exercised its option for continued development of Collaboration Candidate 2 (as defined under the Ono Agreement). The Company elected its Co-Development Co-Commercialization option (CDCC Option) for Collaboration Candidate 2. As a result, we are entitled to receive an Option Exercise Payment (as defined under the Ono Agreement) of $12.5 million. We determined the exercise represented an option with no material right under the Ono Agreement. We have completed our performance obligations with respect to the exercise of the option and accordingly, recognized the Option Exercise Payment as revenue for the year ended December 31, 2022.

Subject to Ono's exercise of its options to obtain exclusive licenses to develop and commercialize Candidate 2 or Candidate 3 and to the achievement of certain clinical, regulatory and commercial milestones (the Ono Milestones) with respect to the Candidate in specified territories, we are entitled to receive an aggregate of up to $843.0 million in additional milestone payments for each Candidate, with the applicable milestone payments for the United States and Europe subject to reduction by 50% if we elect to co-develop and co-commercialize the Candidate as described above. As of December 31, 2022, we have not received any milestone payments other than the $10.0 million associated with the Ono Letter Agreement in December

December 31, 2022, we have not received any milestone payments other than the $10.0 million associated with the Ono Letter Agreement in December 2020. We are also eligible to receive tiered royalties ranging from the mid-single digits to the low-double digits based on annual net sales by Ono for each Candidate in specified territories, with such royalties subject to certain reductions. As of December 31, 2022, no royalties have been paid to us under the Ono Agreement, the Ono Letter Agreement or the Ono Amendment.

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As a direct result of our entry into the Ono Agreement, the Ono Letter Agreement and the Ono Amendment, we incurred an aggregate of $7.8 million in sublicense consideration to certain of our existing licensors, of which $4.0 million has been paid as of December 31, 2022. The $7.8 million in sublicense consideration represents an asset under ASC 340, *Other Assets and Deferred Costs* and is amortized to research and development expense ratably with our revenue recognition under the Ono Agreement.

Memorial Sloan Kettering Cancer Center License Agreement

On May 15, 2018, we entered into the Amended MSK License with MSK. The Amended MSK License amended and restated the Exclusive License Agreement entered into between us and MSK on August 19, 2016, pursuant to which we entered into an exclusive license agreement with MSK for rights relating to compositions and methods covering iPSC-derived cellular immunotherapy, including T-cells and NK-cells derived from iPSCs engineered with CARs.

Pursuant to the Amended MSK License, MSK granted us additional licenses to certain patents and patent applications relating to new CAR constructs and off-the-shelf CAR T cells, including the use of clustered regularly interspaced short palindromic repeat (CRISPR) and other innovative technologies for their production, in each case to research, develop, and commercialize licensed products in the field of all human therapeutic uses worldwide. We have the right to grant sublicenses to certain licensed rights in accordance with the terms of the Amended MSK License, in which case we are obligated to pay MSK a percentage of certain sublicense income received.

In the event a licensed product achieves a specified clinical milestone, MSK is then eligible to receive certain milestone payments totaling up to $75.0 million based on the price of our common stock, where the amount of such payments owed to MSK is contingent upon certain increases in the price of our common stock following the date of achievement of such clinical milestone. These payments are based on common stock price multiples, with the numerator being the fair value of the ten-trading day trailing average closing price of our common stock and the denominator being the ten-trading day trailing average closing price of our common stock as of the effective date of the Amended MSK License, adjusted for any stock splits, cash dividends, stock dividends, other distributions, combinations, recapitalizations, or similar events. Under the terms of the Amended MSK License, upon a change of control of our company, in certain circumstances, we may be required to pay a portion of these payments to MSK based on the price of our common stock in connection with such change of control.

As of December 31, 2022, we recorded a liability of $3.9 million associated with the remaining stock price appreciation milestones for the Amended MSK License. In July 2021, we achieved a specified clinical milestone for a licensed product under the Amended MSK License and our ten-trading day trailing average common stock price exceeded the first, pre-specified threshold. As a result, we remitted the first milestone payment of $20.0 million to MSK during the year ended December 31, 2021. January 2023.

Investing Activities

During the years ended December 31, 2022 December 31, 2023 and 2021, 2022, investing activities provided cash of $166.8 million $112.7 million and used cash $166.8 million, respectively. During the year ended December 31, 2023 we purchased $358.8 million of $324.0 million, respectively. investments, which were partially offset by $477.6 million in maturities of investments. During the year ended December 31, 2022 we purchased $404.8 million of investments, which were partially offset by $607.1 million in maturities of investments. During the year ended December 31, 2021, we purchased $968.2 million of investments, offset by $694.8 million in maturities of investments. The remaining investing activities for the periods presented were primarily attributable to the purchase of property and equipment.

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Financing Activities

Financing activities provided cash of $0.1 million for the year ended December 31, 2023, which consisted of $0.1 million received from the issuance of common stock from equity incentive plans pursuant to the exercise of employee stock options.

Financing activities provided cash of $9.2 million for the year ended December 31, 2022, which primarily consisted of $9.2 million received from the issuance of common stock from equity incentive plans pursuant to the exercise of employee stock options.

Financing activities provided cash of $453.1 million for the year ended December 31, 2021, which primarily consisted of $432.4 million of net proceeds from our January 2021 public offering of common stock and issuance of pre-funded warrants and $20.7 million received from the issuance of common stock from equity incentive plans pursuant to the exercise of employee stock options.

From our inception through December 31, 2022 December 31, 2023 we have funded our consolidated operations primarily through the public and private sale of common stock, the private placement of preferred stock and convertible notes, commercial bank debt and revenues from collaboration activities and grants. As of December 31, 2022 December 31, 2023, we had aggregate cash and cash equivalents and investments of $441.2 million $316.2 million.

Private Placement of Common Stock

In June 2020, in connection with the June 2020 public offering of common stock, we exercised our right to cause an existing shareholder, Johnson & Johnson Innovation-JJDC, Inc (JJDC) to purchase $50.0 million of our common stock, and JJDC purchased in a private placement 1.8 million shares of our common stock at a price of $28.31 per share, for aggregate proceeds of $50.0 million. In

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April 2020, we entered into a Stock Purchase Agreement with JJDC. Under the Stock Purchase Agreement, we sold 1.6 million shares of our common stock to JJDC at $31.00 per share, for an aggregate purchase price of $50.0 million. The shares of common stock purchased as part of these private placements were not subject to underwriting discounts or commissions.

Public Offerings of Common Stock

In June 2020, we completed a public offering of common stock in which investors, certain of which are affiliated with one of our directors, purchased 7.1 million shares of our common stock at a price of $28.31 per share under a shelf registration statement. Gross proceeds from the offering were $201.3 million. After giving effect to $12.5 million in underwriting discounts, commissions and expenses related to the offering, net proceeds were $188.8 million.

In January 2021, we completed a public offering of common stock in which investors, certain of which are affiliated with one of our directors, purchased 5.1 million shares of our common stock at a price of $85.50 per share under a shelf registration statement. In addition, we issued pre-funded warrants, in lieu of common stock to certain investors, to purchase 257,310 shares of our common stock (Pre-Funded Warrants). The purchase price of for the Pre-Funded Warrants was $85.499 per Pre-Funded Warrant, which equals the per share public offering price for the shares of common stock less the $0.001 exercise price for each such Pre-Funded Warrant. See Note 9 of the notes to our consolidated financial statements for additional detail. Gross proceeds from the public offering and the issuance of the Pre-Funded Warrants were $460.0 million. After giving effect to $27.6 million in underwriting discounts, commissions and expenses related to the public offering and the issuance of Pre-Funded Warrants, net proceeds were $432.4 million.

California Institute for Regenerative Medicine Award

On April 5, 2018, we executed an award agreement with the California Institute for Regenerative Medicine (CIRM) pursuant to which CIRM awarded us $4.0 million to advance our FT516 product candidate into a first-in-human clinical trial (the Award). In November 2019, we submitted an IND application for FT516 in advanced solid tumors. As of December 31, 2022, we have received all disbursements available under the Award in the amount of $4.0 million.

The Award is subject to certain co-funding requirements by us. We, in our sole discretion, have the option to treat the Award either as a loan or as a grant. In the event we elect to treat the Award as a loan, we will be obligated to repay i) 60%, ii) 80%, iii) 100% or iv) 100% plus interest at 7% plus LIBOR, of the total Award to CIRM, where such repayment rate is dependent upon the phase of clinical development of FT516 at the time of our election. If we do not elect to treat the Award as a loan within 10 years of the date of the Award, the Award will be considered a grant and we will be obligated to pay to CIRM a royalty on commercial sales of FT516 until such royalty payments equal nine times the total amount awarded to us under the Award.

Registration Statements on Form S-3

In November 2021, we filed an automatic 2023, the SEC declared effective a shelf registration statement on Form S-3 filed by us in November 2023 (File No. 333-260772), which became effective upon filing. 333-275402). The shelf registration statement allows us to issue certain securities, including shares of our common stock, from time to time. The specific terms of any offering under the automatic shelf registration statement are would

be established at the time of such offering. We are eligible to issue an aggregate of $300.0 million in securities under the shelf registration statement.

Additionally, we entered into a sales agreement with Jefferies Group LLC (Jefferies) with respect to an at-the-market offering program, under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to $350.0 million $100.0 million (which is included in the $300.0 million registered under the shelf registration statement) through Jefferies as the sales agent, agent. To date, we have not sold any securities pursuant to this automatic the sales agreement with Jefferies or the shelf registration statement.

Operating Capital Requirements

We anticipate that we will continue to incur losses for the foreseeable future, and we expect the losses to increase remain significant as we continue the research, manufacture and development of, and seek regulatory approvals for, our product candidates and conduct additional research, manufacturing and development activities pursuant to our collaboration agreement with Ono. Our product candidates have not yet achieved regulatory approval and we may not be successful in achieving commercialization of our product candidates.

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We believe our existing cash and cash equivalents and investments as of December 31, 2022 will be sufficient to fund our projected operating requirements for at least the next twelve months. However, we are also subject to all the risks and uncertainties incident in the research, manufacture and development of therapeutic products, and cell therapy product candidates in particular. For example, the FDA or other regulatory authorities may require us to generate additional data or conduct additional preclinical studies, manufacturing activities, or clinical trials, or may impose other requirements beyond those that we currently anticipate. Additionally, it is possible for a product candidate to show promising results in preclinical studies or in clinical trials, but fail to establish sufficient safety and efficacy data necessary to obtain regulatory approvals. As a result of these and other risks and uncertainties and the probability of success, the duration and the cost of our research, manufacturing and development activities required to advance a product candidate cannot be accurately estimated and are subject to considerable variation. We may encounter difficulties, complications, delays and other unknown factors and unforeseen expenses in the course of our research, manufacturing and development activities, any of which may significantly increase our capital requirements and could adversely affect our liquidity.

We will require additional capital for the research, manufacture and development of our product candidates and to perform our obligations under our existing collaboration agreements, and any additional collaboration agreements that we may enter into, and we may need to seek additional funds sooner than expected due to any changes in our business, operations, financial condition or prospects, including any impacts of the COVID-19 pandemic or other global pandemics or epidemics, inflation rates and global economic conditions, and the ongoing conflict in Ukraine. wars or other armed conflicts. We expect to finance our capital requirements in the foreseeable future through the sale of public or private equity, debt securities, or debt securities. through existing or future potential collaborations. However, additional capital may not be available to us on reasonable terms, if at all. 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 research, manufacture or development of one or more of our product candidates. If we do raise additional funds through the issuance of additional equity or debt securities, it could result in dilution to our existing stockholders, increased fixed payment obligations and interest payment obligations and the existence of securities with rights that may be senior to those of our common stock. Additionally, if we incur indebtedness, we may become subject to financial or other covenants that could adversely restrict, impair or affect our ability to conduct our business, such as requiring us to relinquish rights to certain of our product candidates or technologies or limiting our ability to acquire, sell or license intellectual property rights or incur additional debt. Any of these events could significantly harm our business, operations, financial condition and prospects. In addition, while the full impact of inflation rates, global political and economic instability, a continued and prolonged public health emergency such as the COVID-19 pandemic, inflation rates, and the ongoing conflict in Ukraine wars and other armed conflicts, on our business, operations, financial condition and prospects, and on the global economy, are currently unknown and difficult to predict, the pandemic has caused significant disruptions and created uncertainties in the global financial markets, and the economic impacts of the pandemic, rising inflation rates and global economic conditions, or the Ukrainian conflict these events could materially and adversely affect our ability to raise capital through equity or debt financings in the future.

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Our forecast of the period of time through which our existing cash and cash equivalents and investments will be adequate to support our operations is a forward-looking statement and involves significant risks and uncertainties. We have based this forecast on assumptions that may prove to be wrong, and actual results could vary materially from our expectations, which may adversely affect our capital resources and liquidity. We could utilize our available capital resources sooner than we currently expect. The amount and timing of future funding requirements, both near- and long-term, will depend on many factors, including, but not limited to:

will depend on many factors, including, but not limited to:

- the initiation, timing, progress, size, duration, costs and results of our clinical trials and preclinical studies for our product candidates; candidates, including the timing and costs of manufacturing activities to support such clinical trials and preclinical studies;
- the number and the nature of product candidates that we pursue;
- the time to and cost of establishing and maintaining internal GMP production capabilities to support the clinical and potential commercial manufacture of our product candidates at our new corporate headquarters;
- the cost of GMP production, process and scale-up development and technology transfer activities for the manufacture of our product candidates, including the cost of laboratory equipment, materials and supplies to support these activities;
- the time, cost and outcome of seeking and obtaining regulatory approvals;
- the extent to which we are required to pay milestone or other payments under our existing in-license agreements and any in-license agreements that we may enter into in the future, and the timing of such payments, including payments owed to MSK MSKCC in connection with the stock price appreciation milestones;
- the extent to which milestones are achieved under our collaboration agreement with Ono, and any other strategic partnership or collaboration agreements that we may enter into in the future, and the time to achievement of such milestones and our receipt of any associated milestone payments;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, including in our ongoing lawsuits against Shoreline Biosciences, Inc. (Shoreline) and Dr. Dan S. Kaufman (Kaufman), and the cost of enforcing any of our other contractual rights;

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- the cost of our research and development activities, including our need and ability to hire additional employees and procure additional equipment, materials and supplies;
- the establishment and continuation of collaborations and strategic alliances;
- the timing and terms of future in-licensing and out-licensing transactions; and
- the cost of establishing sales, marketing, manufacturing and distribution capabilities for, and the pricing and reimbursement of, any products for which we may receive regulatory approval.

In addition, we are closely monitoring ongoing developments in connection with the COVID-19 pandemic, inflation rates and global political and economic conditions, and including the ongoing conflict in wars between Russia and Ukraine and between Israel and Hamas, and evaluating adjustments to our business and operations, which may negatively impact our financial condition and prospects and our operating results. We will continue to assess our operating capital requirements and may make adjustments to our business and operations if circumstances warrant. If we cannot continue or expand our research, manufacturing and development operations, or otherwise capitalize on our business opportunities, because we lack sufficient capital, our business, operations, financial condition and prospects could be materially adversely affected.

As a result of the termination of the Janssen Agreement and the NK cell program prioritization, during the first quarter of 2023, we expect an increase in revenue associated with the Janssen Agreement termination and additionally expect that we will incur charges of approximately $12 million to $16 million for severance and other employee termination-related costs. However, we expect revenue and overall expenses to decrease in 2023 due to a corporate restructuring and prioritization of programs. The restructuring is expected to extend our cash runway into the second half of 2025.

Contractual Obligations and Commitments

We lease certain office, laboratory, and manufacturing space under non-cancelable operating leases. In addition to rent, our leases are subject to certain fixed amenities fees. These leases are also subject to additional variable charges for common area maintenance, property taxes, property insurance and other variable costs. See Note 8 of the consolidated financial statements for additional detail.

Total undiscounted aggregate future operating lease obligations under all of our operating leases as of December 31, 2022 December 31, 2023 are $177.7 million $162.9 million.

On May 15, 2018, we entered into the Amended MSKCC License with MSKCC. In the event a licensed product achieves a specified clinical milestone, MSKCC is then eligible to receive certain milestone payments totaling up to $75.0 million based on the price of our common stock, where the amount of such payments owed to MSKCC is contingent upon certain increases in the price of our common stock following the date of achievement of such clinical milestone. See Note 2 of the consolidated financial statements for additional detail.

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As of December 31, 2023, we recorded a liability of $1.3 million associated with the remaining stock price appreciation milestones for the Amended MSKCC License.

We have no material contractual obligations not fully recorded on our consolidated balance sheets or fully disclosed in the notes to the financial statements.

We have obligations under various license agreements to make future payments to third parties that become due and payable on the achievement of certain development, regulatory and commercial milestones (such as the start of a clinical trial, filing for product approval with the FDA or other regulatory agencies, product approval by the FDA or other regulatory agencies, product launch or product sales) or on the sublicense of our rights to another party. We have not included these commitments on our balance sheet because the achievement and timing of these events is not fixed and determinable. Certain milestones are in advance of receipt of revenue from the sale of products and, therefore, we may require additional debt or equity capital to make such payments. These commitments include:

- Under a license agreement with the Whitehead Institute for Biomedical Research, pursuant to which we license certain patents relating to our iPSC product platform, we are required to make annual maintenance payments and payments based upon development, regulatory and commercial milestones for any products covered by the in-licensed intellectual property. The maximum aggregate milestone payments we may be obligated to make per product are $2.3 million. We will also be required to pay a royalty on net sales of products covered by the in-licensed intellectual property in the low single digits. The royalty is subject to reduction for any third-party payments required to be made, with a minimum floor in the low single digits. We have the right to sublicense our rights under this agreement, and we will be required to pay a percentage of any sublicense income.
- Under license agreements with The Scripps Research Institute (TSRI), pursuant to which we license certain patents relating to our iPSC product platform, we are required to make annual maintenance payments and payments based upon development, regulatory and commercial milestones for any products covered by the in-licensed intellectual property. The maximum aggregate milestone payments we may be obligated to make are $1.8 million. We will also be required to pay a royalty on net sales of products covered by the in-licensed intellectual property in the low- to mid-single digits. The royalty is subject to reduction for any third-party payments required to be made, with a minimum floor in the low single digits. We have the right to sublicense our rights under these agreements, and we will be required to pay a percentage of any sublicense income.

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- Under a license agreement with the Regents of the University of Minnesota, pursuant to which we license certain patents relating to compositions and uses of NK cells and to compositions of engineered receptors and immune cells expressing such receptors, we are required to make annual maintenance payments and payments based upon development, regulatory and commercial milestones for any products covered by the in-licensed intellectual property. The maximum aggregate milestone payments we may be obligated to make per product are $4.6 million. We will also be required to pay a royalty on net sales of products covered by the in-licensed intellectual property in the low single digits. The royalty is subject to reduction for any third-party payments required to be made, with a minimum floor in the low single digits. We have the right to sublicense our rights under this agreement, and we will be required to pay a percentage of any sublicense income.
- Under a license agreement with Memorial Sloan Kettering Cancer Center, MSKCC, pursuant to which we license certain patents relating to compositions and uses of T cells T-cells derived from iPSCs, CARs and genetic modifications using CRISPR, we are required to make annual maintenance payments and payments based upon development, regulatory and commercial milestones for any products covered by the in-licensed intellectual property. The maximum aggregate milestone payments we may be obligated to make per product are $12.5 million. We will also be required to pay a royalty on net sales of products covered by the in-licensed intellectual property up to the high-single digits. The royalty is subject to reduction for any third-party payments required to be made, with a minimum floor in the low- to mid-single digits. We have the right to sublicense our rights under this agreement, and we will be required to pay a percentage of any sublicense income. Additionally, in the event a licensed product achieves a specified clinical milestone, Memorial Sloan Kettering Cancer Center MSKCC is then eligible to receive additional milestone payments, where the amount of such payments owed to Memorial Sloan Kettering Cancer Center MSKCC are contingent upon certain increases in the price of our common stock following the date of achievement of such clinical milestone. See Note 2 of the notes to the consolidated financial statements for additional detail related to the stock price appreciation milestone payments.
- Under a license agreement with Dana Farber Cancer Institute, pursuant to which we license certain patent applications relating to novel antibody fragments that bind the alpha-3 domain of MICA/B, we are required to make annual maintenance payments and payments based upon development, regulatory and commercial milestones for any products covered by the in-licensed intellectual property. The maximum aggregate milestone payments we may be obligated to make per product are $25 million. We will also be required to pay a royalty on net sales of products covered by the in-licensed intellectual property in the low single digits. The royalty is subject to reduction for any third-party payments required to be made, with a minimum floor in the low single digits. We have the right to sublicense our rights under these agreements, and we will be required to pay a percentage of any sublicense income.

- Under a license agreement with Max Delbruck Center for Molecular Medicine (MDC), pursuant to which we license certain patents relating to novel humanized antibody fragments, antigen-binding domains and CAR constructs that uniquely target and specifically bind B-cell Maturation Antigen, we are required to make annual maintenance payments and payments based upon development, regulatory and commercial milestones for any products covered by the in-licensed intellectual property. The maximum aggregate milestone payments we may be obligated to make per product are $11.0 million. We will also be required to pay a royalty on net sales of products covered by the in-licensed intellectual property in the low single digits. The royalty is subject to reduction for any third-party payments required to be made, with a minimum floor in the low single digits. We have the right to sublicense our rights under this agreement, and we will be required to pay a percentage of any sublicense income.
- Under a license agreement with Baylor College of Medicine, pursuant to which we license certain patents relating to the composition and use of a novel allo-immune defense receptor (ADR), we are required to make annual maintenance payments and payments based upon development, regulatory and commercial milestones for any products covered by the in-licensed intellectual property. The maximum aggregate milestone payments we may be obligated to make per product are $7.0 million. We will also be required to pay a royalty on net sales of products covered by the in-licensed intellectual property in the low single digits. The royalty is subject to reduction for any third-party payments required to be made, with a minimum floor in the low single digits. We have the right to sublicense our rights under this agreement, and we will be required to pay a percentage of any sublicense income.

We enter into contracts in the normal course of business, including with clinical sites, CROs, and other professional service providers for the conduct of clinical trials, contract manufacturers for the production of our product candidates, contract research service providers for preclinical research studies, professional consultants for expert advice and vendors for the sourcing of clinical and laboratory supplies and materials. These contracts generally provide for termination on notice, and therefore are cancelable contracts and not included in the table of contractual obligations and commitments.

Inflation

Inflation has increased during the periods covered by this Annual Report on Form 10-K, and is expected to may continue to increase or remain elevated for the near future. Inflationary factors, such as increases in the prices of material, interest rates and cost of labor may adversely affect our operating results. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, we may experience some effect in the near future, especially if inflation rates continue to rise.

ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk Not applicable to smaller reporting companies.

We are exposed to market risk primarily related to changes in interest rates. As of December 31, 2022, our cash and cash equivalents consisted of cash and money market mutual funds, and our investments consisted of United States treasuries and corporate debt securities with maturities up to eighteen months from the date of acquisition. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the relatively short-term nature and low risk profile of the instruments in our portfolio, a 10% change in market interest rates would not have a material impact on our financial condition and/or results of operations. 92

Stock Price Sensitivity

We entered into a license agreement with MSK under which we obtained rights relating to compositions and methods covering iPSC-derived cellular immunotherapy, including T cells and NK cells derived from iPSCs engineered with CARs. MSK is eligible to receive certain milestone payments totaling up to $75.0 million in the event a licensed product achieves a specified clinical milestone, where the amount of such payments owed to MSK is contingent upon certain increases in the price of our common stock following the date of achievement of such clinical milestone. As of December 31, 2022, the estimated fair value of the stock price appreciation milestones was $3.9 million. In July 2021, we achieved a specified clinical milestone for a licensed product under the Amended MSK License and our ten-trading day trailing average common stock price exceeded the first, pre-specified threshold. As a result, we remitted the first milestone payment of $20.0 million to MSK during the year ended December 31, 2021.

Changes in the price our common stock as of each balance sheet date may cause a relatively large change in the estimated fair value of the stock price appreciation milestones and the associated liability and resulting expense or gain. See Note 5 to our consolidated financial statements for a

related sensitivity analysis.

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ITEM 8. Financial Statements and Supplementary Data

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Fate Therapeutics, Inc Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Fate Therapeutics, Inc. as of December 31, 2022 December 31, 2023 and 2021, 2022, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity and cash flows for each of the three two years in the period ended December 31, 2022 December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 December 31, 2023 and 2021, 2022, and the results of its operations and its cash flows for each of the three two years in the period ended December 31, 2022 December 31, 2023, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control- Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 28, 2023, expressed an unqualified opinion thereon.

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 based on our audits. We are a public accounting firm registered with the 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 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 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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below providing a separate opinion on the critical audit matter or on the account or disclosure to which it relates.

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Revenue recognition ***Accrued research and development expenses – Revenue Recognized Over Time*** ***clinical trials***

Description of the Matter

As more fully described in Note 2 of the financial statements, the The Company has concluded that the grant of intellectual property licenses and the delivery of related recorded research and development services under expenses of $172.6 million for the year ended December 31, 2023. Research and development costs are expensed as incurred. Research and development costs include fees paid to contract research organizations, investigative sites and sponsored research organizations that conduct certain research and development activities on the Company's behalf for clinical trials.

Auditing the Company's research and development expenses and related accruals was challenging due to the complex nature of its existing collaboration agreements represent a combined performance obligation for which evaluating the Company recognizes collaboration revenues completeness and accuracy of the expenses and accruals. Research and development expenses are recognized as the research services are transferred being performed by the vendors, which requires management to accurately estimate the time period over time. Revenue is recognized over the estimated period of time to conduct the research which services based on an appropriate measure of progress towards satisfaction of the identified performance obligation. Collaboration revenue is significant to our audit because the revenue recognition assessment process involves inherent uncertainty, uses subjective assumptions, will be performed and the amounts involved are material to the financial statements taken as a whole. The subjective assumptions relate to the estimated total full-time employees (FTEs) expected level of effort to be utilized as well as the assumed timing and duration of the underlying activities. expended in each period.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated To test the design, clinical trial expenses and tested related accruals, our audit procedures included, among others, confirming with a sample of vendors the operating effectiveness progress of controls over activities under research and development contracts at period end, testing a sample of cash disbursements after period end to assess the Company's revenue recognition review process including controls over management's review completeness of the significant assumptions described above. For example, we tested controls over the development of the estimated FTEs through the completion of the contract and the review of the estimates by management.

To test revenue recognized we performed audit procedures that included, among other things, testing the assumptions and underlying data used by the Company in its computations expense recognition, and testing a sample of research and development expenses recorded during the accuracy of the computations. We inspected evidence supporting actual FTEs utilized period and assessed whether they were appropriately included according to the terms of the contract. We corroborated management's estimates and judgements by performing sensitivity analyses of key inputs and inspecting communications between the Company and its collaborators regarding updates to budgeted FTEs and contract modifications that would impact evaluating the timing and duration amount of the collaboration. We performed corroborative inquiries of individuals outside of the finance department to assess the basis for the key assumptions utilized as of the reporting date based on current factors. expense recognition.

/s/ Ernst & Young, LLP

We have served as the Company's auditor since 2009.

San Diego, California

February 28, 2023 26, 2024

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Fate Therapeutics, Inc.

Consolidated Balance Sheets

(In thousands, except par value and share data)

	December 31,		December 31,	
	2022	2021	2023	2022
Assets				
Current assets:				
Cash and cash equivalents	$ 61,333	$ 133,583	$ 41,870	$ 61,333
Accounts receivable	38,480	8,676	1,826	38,480
Short-term investments	374,894	482,327	273,305	374,894
Prepaid expenses and other current assets	27,367	8,826	14,539	27,367
Total current assets	502,074	633,412	331,540	502,074
Long-term investments	4,942	100,664	980	4,942
Property and equipment, net	110,020	91,529	96,836	110,020
Operating lease right-of-use assets	66,069	70,720	61,675	66,069
Restricted cash	15,227	15,227	15,177	15,227
Collaboration contract assets	7,196	9,870	—	7,196
Other assets	33	33	9	33
Total assets	$ 705,561	$ 921,455	$ 506,217	$ 705,561
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable	$ 8,265	$ 8,612	$ 4,719	$ 8,265
Accrued expenses	53,932	42,412	27,514	53,932
CIRM award liability, current portion	4,000	3,200		
Deferred revenue, current portion	42,226	21,483		
CIRM award liability			—	4,000
Deferred revenue			685	42,226
Operating lease liabilities, current portion	5,628	5,577	6,176	5,628
Total current liabilities	114,051	81,284	39,094	114,051
Deferred revenue, net of current portion	—	27,124		
CIRM award liability, net of current portion	—	800		
Operating lease liabilities, net of current portion	103,710	109,241	97,360	103,710
Stock price appreciation milestones, net of current portion	3,861	24,168		
Stock price appreciation milestones			1,346	3,861
Commitments and contingencies				
Stockholders' equity:				
Preferred stock, $0.001 par value; authorized shares—5,000,000 at December 31, 2022 and December 31, 2021; Class A Convertible Preferred shares issued and outstanding—2,794,549 at December 31, 2022 and December 31, 2021	3	3		
Common stock, $0.001 par value; authorized shares—250,000,000 at December 31, 2022 and December 31, 2021; issued and outstanding—97,294,917 at December 31, 2022 and 95,726,962 at December 31, 2021	97	96		
Preferred stock, $0.001 par value; authorized shares—5,000,000; Class A Convertible Preferred shares issued and outstanding—2,761,108 at December 31, 2023 and				

2,794,549 at December 31, 2022			3	3
Common stock, $0.001 par value; authorized shares—250,000,000; issued and outstanding— 98,627,076 at December 31, 2023 and 97,294,917 at December 31, 2022			99	97
Additional paid-in capital	1,536,497	1,448,584	1,580,032	1,536,497
Accumulated other comprehensive loss	(1,854)	(762)		
Accumulated other comprehensive income (loss)			15	(1,854)
Accumulated deficit	(1,050,804)	(769,083)	(1,211,732)	(1,050,804)
Total stockholders' equity	483,939	678,838	368,417	483,939
Total liabilities and stockholders' equity	$ 705,561	$ 921,455	$ 506,217	$ 705,561

See accompanying notes.

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Fate Therapeutics, Inc.

Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share data)

	For the Years Ended December 31,			For the Years Ended December 31,	
	2022	2021	2020	2023	2022
Collaboration revenue	$ 96,300	$ 55,846	$ 31,434	$ 63,533	$ 96,300
Operating expenses:					
Research and development	320,454	215,519	125,623	172,596	320,454
General and administrative	84,232	57,321	33,896	81,448	84,232
Total operating expenses	404,686	272,840	159,519	254,044	404,686
Loss from operations	(308,386)	(216,994)	(128,085)	(190,511)	(308,386)
Other income (expense):					
Other income:					
Interest income	5,842	1,309	2,400	17,186	5,842
Change in fair value of stock price appreciation milestones	20,307	3,534	(47,702)	2,515	20,307
Other income	516	—	—	9,882	516
Total other income (expense), net	26,665	4,843	(45,302)		
Total other income				29,583	26,665
Net loss	$ (281,721)	$ (212,151)	$ (173,387)	$ (160,928)	$ (281,721)
Other comprehensive (loss) gain:					
Unrealized (loss) gain on available-for-sale securities, net	(1,092)	(832)	48		
Other comprehensive gain (loss):					
Unrealized gain (loss) on available-for-sale securities, net				1,869	(1,092)

securities, net				1,809	(1,092)
Comprehensive loss	$ (282,813)	$ (212,983)	$ (173,339)	$ (159,059)	$ (282,813)
Net loss per common share, basic and diluted	$ (2.91)	$ (2.24)	$ (2.10)	$ (1.64)	$ (2.91)
Weighted–average common shares used to compute basic and diluted net loss per share	96,826,058	94,747,311	82,385,319	98,411,162	96,826,058

See accompanying notes.

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Fate Therapeutics, Inc.

Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity

(In thousands, except share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated Other Comprehensive Gain (Loss)	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital			Equity	Shares	Amount	Shares	Amount	Capital	Gain (Loss)	Deficit	Equity
Balance at December 31, 2019	2,794,549	$ 3	75,730,260	$ 76	$ 628,200	$ 2	$ (383,545)	$ 244,756								
Exercise of stock options, net of issuance costs	—	—	1,419,117	1	9,581	—	—	9,582								

Issuance of common stock upon vesting of restricted stock units	—	—	85,000	—	—	—	—	—
Stock–based compensation	—	—	—	—	30,753	—	—	30,753
Public offering of common stock, net of offering costs	—	—	7,108,796	7	188,777	—	—	188,784
Private placement of common stock, net of issuance costs	—	—	1,766,160	2	49,973	—	—	49,975
Issuance of stock to collaboration partner, net of issuance costs	—	—	1,612,904	2	33,932	—	—	33,934
Unrealized gain on investments	—	—	—	—	—	48	—	48
Net loss	—	—	—	—	—	—	(173,387)	(173,387)
Balance at December 31, 2020	2,794,549	$ 3	87,722,237	$ 8	$ 941,216	$ 70	$ (556,932)	$ 384,445

			2,4															
Exercise of stock options, net of issuance costs	—	—	3 0, 2 9 8	2	2 0, 7 2 8	—	—	2 0, 7 3 0										
Issuance of common stock upon vesting of restricted stock units	—	—	4 5 1, 6 2 0	1	—	—	—	1										
					5 4, 3			5 4, 3										
Stock–based compensation	—	—	—	—	6 4	—	—	6 4										
Public offering of common stock and issuance of pre-funded warrants, net of offering costs	—	—	5, 1 2 2, 8 0 7	5	4 3 2, 2 7 6	—	—	4 3 2, 8 1										
Unrealized loss on investments, net	—	—	—	—	—	(8 3 2)	—	(8 3 2)										
							(2 1 2, 1 5 1)	(2 1 2, 1 5 1)										
Net loss	—	—	—	—	—	—												
Balance at December 31, 2021	9 2, 7 9 4, 5 9 4 6 9	$ 3	9 5, 7 2 6, 9 2 6 2	$ 6	$ 4 1, 7 4 4 8, 5 8 8	$ 2) (7 6 6	$ 3) (7 6 8 3	$ 8 7 6 7 8, 8 0 8 3	2,794,549	$ 3	95,726,962	$ 96	$ 1,448,584	$ (762)	$ (769,083)	$ 678,838		
Exercise of stock options, net of issuance costs	—	—	9 4 1, 7 8 0	1	9, 1 8 0	—	—	9, 1 8 1	—	—	941,780	1	9,180	—	—	9,181		

Issuance of common stock upon vesting of restricted stock units	—	—	62,165	—	—	—	—	—	—	—	626,175	—	—	—	—	—		
Stock–based compensation	—	—	—	—	78,733	—	—	78,733	—	—	—	—	78,733	—	—	78,733		
Unrealized loss on investments, net	—	—	—	—	—	(1,092)	—	(1,092)	—	—	—	—	—	(1,092)	—	(1,092)		
Net loss	—	—	—	—	—	—	(281,721)	(281,721)	—	—	—	—	—	—	(281,721)	(281,721)		
Balance at December 31, 2022	92,745,439	$ 3	97,162,459	$ 7	$ 761,504	$ (40,810)	$ (1,050,804)	$ 483,939	2,794,549	$ 3	97,294,917	$ 97	$ 1,536,497	$ (1,854)	$ (1,050,804)	$ 483,939		
Exercise of stock options, net of issuance costs	—	—	—	—	—	—	—	—	—	—	93,787	—	76	—	—	76		
Issuance of common stock upon vesting of restricted stock units	—	—	—	—	—	—	—	—	—	—	1,071,167	1	—	—	—	1		
Conversion of preferred shares to common stock	—	—	—	—	—	—	—	—	(33,441)	—	167,205	1	—	—	—	1		
Stock–based compensation	—	—	—	—	—	—	—	—	—	—	—	—	43,459	—	—	43,459		
Unrealized gain on investments, net	—	—	—	—	—	—	—	—	—	—	—	—	—	1,869	—	1,869		
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(160,928)	(160,928)		

Balance at December 31, 2023	2,761,108	$ 3	98,627,076	$ 99	$ 1,580,032	$ 15	$ (1,211,732)	$ 368,417

See accompanying notes

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Fate Therapeutics, Inc.

Consolidated Statements of Cash Flows

(in thousands)

	Years Ended December 31,			Years Ended December 31,	
	2022	2021	2020	2023	2022
Operating activities:					
Net loss	$ (281,721)	$ (212,151)	$ (173,387)	$ (160,928)	$ (281,721)
Adjustments to reconcile net loss to net cash used in operating activities					
Depreciation and amortization	13,758	5,850	3,087	18,282	13,758
Stock–based compensation	78,733	54,364	30,753	43,459	78,733
Accretion and amortization of premiums and discounts on investments, net	(256)	5,067	1,676	(11,398)	(256)
Amortization of collaboration contract asset	2,676	3,995	3,110	7,196	2,676
Deferred revenue	(6,381)	(18,559)	60,603	(41,541)	(6,381)
Change in fair value of stock price appreciation milestones	(20,307)	(3,534)	47,702	(2,515)	(20,307)
Grant income from CIRM award				(4,000)	—
Changes in assets and liabilities:					
Accounts receivable	(29,804)	(3,160)	(5,515)	36,654	(29,804)
Prepaid expenses and other assets	(18,330)	(3,052)	(13,582)	12,876	(18,330)
Accounts payable and accrued expenses	14,252	5,907	(1,554)	(28,940)	14,252
Right-of-use assets and lease liabilities, net	(828)	2,403	7,878	(1,408)	(828)
Net cash used in operating activities	(248,208)	(162,870)	(39,229)	(132,263)	(248,208)
Investing activities					
Purchases of property and equipment	(35,566)	(50,704)	(4,932)	(6,153)	(35,566)
	(404,)	(968,)	(277,)		

Purchases of investments	796	159	344	(358,810)	(404,796)
Maturities of investments	607,113	694,840	121,200	477,628	607,113
Net cash provided by (used in) investing activities	166,751	(324,023)	(161,076)		
Net cash provided by investing activities				112,665	166,751
Financing activities					
Issuance of common stock from equity incentive plans, net of issuance costs	9,207	20,714	9,655	85	9,207
Proceeds from public offering of common stock, net of issuance costs	—	411,735	188,784		
Proceeds from issuance of pre-funded warrants, net of issuance costs	—	20,680	—		
Proceeds from private placement of common stock, net of issuance costs	—	—	49,975		
Proceeds from sale of common stock to collaboration partner, net of issuance costs	—	—	33,934		
Proceeds from CIRM award	—	—	490		
Net cash provided by financing activities	9,207	453,129	282,838	85	9,207
Net change in cash, cash equivalents and restricted cash	(72,250)	(33,764)	82,533	(19,513)	(72,250)
Cash, cash equivalents and restricted cash at beginning of the year	148,810	182,574	100,041	76,560	148,810
Cash, cash equivalents and restricted cash at end of the year	$ 76,560	$ 148,810	$ 182,574	$ 57,047	$ 76,560
Supplemental schedule of noncash investing and financing activities					
Purchases of property and equipment in accounts payable	$ 1,055	$ 4,371	$ 1,486	$ —	$ 1,055
Right-of-use assets obtained in exchange for lease obligations	$ 682	$ 8,600	$ 49,287	$ —	$ 682
Accrued issuance costs included in additional paid-in-capital	$ —	$ 133	$ —		

See accompanying notes.

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Fate Therapeutics, Inc.

Notes to Consolidated Financial Statements

1. Organization and Summary of Significant Accounting Policies

Organization

Fate Therapeutics, Inc. (the Company) was incorporated in the state of Delaware on April 27, 2007 and has its principal operations in San Diego, California. The Company is a clinical-stage biopharmaceutical company dedicated to bringing off-the-shelf, multiplexed-engineered, iPSC-derived

natural killer (NK) and T-cell product candidates cellular immunotherapies to patients for the treatment of cancer and autoimmune disease. diseases.

As of December 31, 2022 December 31, 2023, the Company has devoted substantially all of its efforts to product development, raising capital and building infrastructure and has not generated any revenues from any sales of its therapeutic products. To date, the Company's revenues have been derived from collaboration agreements and government grants.

Public Equity Offerings

In January 2021, the Company completed a public offering of common stock in which investors, certain of which are affiliated with a director of the Company, purchased 5.1 million shares of the Company's common stock at a price of $85.50 per share under a shelf registration statement. In addition, the Company issued pre-funded warrants, in lieu of common stock to certain investors, to purchase 257,310 shares of the Company's common stock (Pre-Funded Warrants). The purchase price of the Pre-Funded Warrants was $85.499 per Pre-Funded Warrant, which equals the per share public offering price for the shares of common stock less the $0.001 exercise price for each such Pre-Funded Warrant. See Note 9 for additional detail. Gross proceeds from the public offering and the issuance of the Pre-Funded Warrants were $460.0 million, and after giving effect to $27.6 million of costs related to the public offering and the issuance of Pre-Funded Warrants, net proceeds were $432.4 million.

In June 2020, the Company completed a public offering of common stock in which investors, certain of which are affiliated with a director of the Company, purchased 7.1 million shares of its common stock at a price of $28.31 per share under a shelf registration statement. Gross proceeds from the offering were $201.3 million, and after giving effect to $12.5 million of costs related to the offering, net proceeds were $188.8 million.

Private Placementsof Common Stock

In June 2020, in connection with the June 2020 public offering of common stock, the Company exercised its right to cause an existing shareholder, Johnson & Johnson Innovation-JJDC, Inc (JJDC), to purchase $50.0 million of the Company's common stock, and JJDC purchased in a private placement 1.8 million shares of the Company's common stock at a price of $28.31 per share, for aggregate proceeds of $50.0 million. In April 2020, in connection with the Janssen Agreement described in Note 2, JJDC purchased in a private placement 1.6 million shares of the Company's common stock at a price of $31.00 per share, for aggregate proceeds of $50.0 million. The shares of common stock purchased in the private placements were not subject to any underwriting discounts or commissions.

Use of Estimates

The Company's consolidated financial statements are prepared in accordance with United States generally accepted accounting principles (U.S. GAAP). The preparation of the Company's consolidated financial statements requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in the Company's consolidated financial statements and accompanying notes. The most significant estimates in the Company's consolidated financial statements relate to its stock appreciation milestone obligations, contracts containing leases, and accrued expenses. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

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Risks and Uncertainties

Due to the global outbreak of SARS-CoV-2, the strain of coronavirus that causes Coronavirus disease 19 (COVID-19), including the emergence of new variants of the virus, the Company experienced impacts on certain aspects of its business, including its clinical trial and research and development activities, during the year ended December 31, 2022. For example, the Company implemented in response to governmental "stay at home" orders and in the interests of public health and safety, and the Company has experienced delays or disruptions in the initiation and conduct of its clinical trials as a result of prioritization of hospital and other medical resources toward pandemic efforts, policies and procedures implemented at clinical sites with respect to the conduct of clinical trials, and other precautionary measures taken in treating patients or in practicing medicine in response to the COVID-19 pandemic. The scope and duration of these delays and disruptions, and the ultimate impacts of COVID-19 on the Company's operations, are currently unknown. The Company is continuing to actively monitor the situation and may take further precautionary and preemptive actions as may be required by federal, state or local authorities or that it determines are in the best interests of public health and safety and that of the Company's patient community, employees, partners, and stockholders. The Company cannot predict the effects that such actions, or the impact of COVID-19 on global business operations and economic conditions, may have on its business, strategy, collaborations, or financial and operating results.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its subsidiaries. To date, the aggregate operations of these subsidiaries have not been significant and all intercompany transactions and balances have been eliminated in consolidation.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating and reportable segment.

Fair Value of Financial Instruments

The Company's financial instruments consist primarily of cash and cash equivalents, marketable securities, accounts receivable, stock price appreciation milestones, accounts payable, and accrued liabilities. The carrying amounts of accounts receivable, accounts payable and accrued liabilities are considered to be representative of their respective fair values because of the relatively short-term nature of those instruments.

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an 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 such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three- tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. The Company reviews the fair value hierarchy classification on a quarterly basis.

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Cash, Cash Equivalents and Restricted Cash

Cash and cash equivalents include cash in readily available checking and savings accounts, money market accounts and money market funds. The Company considers all highly liquid investments with an original maturity of three months or less from the date of purchase to be cash equivalents.

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The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the consolidated balance sheets that sum to the total of the same such amounts shown in the consolidated statements of cash flows as of December 31, 2022, 2021 December 31, 2023 and 2020 2022 (in thousands):

	Years Ended December 31,			Years Ended December 31,	
	2022	2021	2020	2023	2022
Cash and cash equivalents	61,333	133,583	167,347	$ 41,870	$ 61,333
Restricted cash	15,227	15,227	15,227	15,177	15,227
Total cash, cash equivalents, and restricted cash shown in the consolidated statement of cash flows	76,560	148,810	182,574	$ 57,047	$ 76,560

For the years ended December 31, 2022, 2021 December 31, 2023 and 2020, 2022, the restricted cash balance includes cash-collateralized irrevocable standby letters of credit for $15.2 million associated with the Company's facilities leases.

Investments

Investments are accounted for as available-for-sale securities and are carried at fair value on the consolidated balance sheets. Upon initial recognition of the investment and at each reporting period, the Company evaluates whether any unrealized losses on investments are attributable to a credit loss or other factors. Any unrealized losses attributable to credit loss are recorded through an allowance for credit losses, limited to the amount by which the fair value is below amortized cost, with the offsetting amount recorded in other income or expense in the consolidated statement of operations and comprehensive loss. Unrealized losses not attributable to an expected credit loss and unrealized gains on investments are recorded in other comprehensive income (loss) on the consolidated statements of operations and comprehensive loss. Realized gains and losses, if any, on investments classified as available-for-sale securities are included in other income or expense.

The amortized cost of investments classified as available-for-sale debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to a significant concentration of credit risk, consist primarily of cash and cash equivalents and investments. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits and investments are held.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets (generally two to five years) and generally consist of furniture and fixtures, computers, scientific and office equipment, and in-process costs related to facilities construction. Repairs and maintenance costs are charged to expense as incurred.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss is recorded if and when events and circumstances indicate that assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amount of those assets. If the carrying amount is not recoverable, the Company measures the amount of any impairment by comparing the carrying value of the asset to the present value of the expected future cash flows associated with the use of the asset. While the Company's current and historical operating losses and negative cash flows are indicators of impairment, management believes that future cash flows to be

received support the carrying value of its long-lived assets and, accordingly, has not recognized any impairment losses since the Company's inception.

Leases

The Company determines if a contract contains a lease at the inception of the contract. The Company currently has leases related to its facilities leased for office and laboratory space, which are classified as operating leases. These leases result in operating

right-of-use (ROU) assets, current operating lease liabilities, and non-current operating lease liabilities in the Company's consolidated balance sheets. The Company does not have any financing leases. Leases with a term of 12 months or less are considered short-term and ROU assets and lease obligations are not recognized. Payments associated with short-term leases are expensed on a straight-line basis over the lease term.

Lease liabilities represent an obligation to make lease payments arising from the lease and ROU assets represent the right to use the underlying asset identified in the lease for the lease term. Lease liabilities are measured at the present value of the lease payments not yet paid discounted using the discount rate for the lease established at the lease commencement date. To determine the present value, the implicit rate is used when readily determinable. For those leases where the implicit rate is not provided, the Company determines an incremental borrowing rate based on

the information available at the lease commencement date in determining the present value of lease payments. ROU assets are measured as the present value of the lease payments and also include any prepaid lease payments made and any other indirect costs incurred, and exclude any lease incentives received. Lease terms may include the impact of options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for operating leases is recognized on a straight-line basis over the lease term. The Company aggregates all lease and non-lease components for each class of underlying assets into a single lease component.

Collaborative Arrangements

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC Topic 808, *Collaborative Arrangements* ("ASC 808") (ASC 808), to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards that are dependent on the commercial success of such activities. To the extent the arrangement is within the scope of ASC 808, the Company assesses whether aspects of the arrangement between the Company and its collaboration partner are within the scope of other accounting literature, including ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606") (ASC 606). If it is concluded that some or all aspects of the arrangement represent a transaction with a customer, the Company will account for those aspects of the arrangement within the scope of ASC 606.

ASC 808 provides guidance for the presentation and disclosure of transactions in collaborative arrangements, but it does not provide recognition or measurement guidance. Therefore, if the Company concludes a counterparty to a transaction is not a customer or otherwise not within the scope of ASC 606, the Company considers the guidance in other accounting literature as applicable or by analogy to account for such transaction. The classification of transactions under the Company's arrangements is determined based on the nature and contractual terms of the arrangement along with the nature of the operations of the participants.

Revenue Recognition

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards that are dependent on the commercial success of such activities. If the Company concludes that some or all aspects of the arrangement represent a transaction with a customer, the Company accounts for those aspects of the arrangement within the scope of ASC 606.

For arrangements attributable to ASC 606, the Company recognizes revenue in a manner that depicts the transfer of control of a product or a service to a customer and reflects the amount of the consideration the Company is entitled to receive in exchange for such product or service. In doing so, the Company follows a five-step approach for arrangements that are attributable to ASC 606 - Revenues from customers: approach: (i) identify the contract with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations, and (v) recognize revenue when (or as) the customer obtains control of the product or service. The Company considers the terms of a contract and all relevant facts and circumstances when applying the revenue recognition standard. The Company applies the revenue recognition standard, including the use of any practical expedients, consistently to contracts with similar characteristics and in similar circumstances.

A customer is a party that has entered into a contract with the Company, where the purpose of the contract is to obtain a product or a service that is an output of the Company's ordinary activities in exchange for consideration. To be considered a contract, (i) the contract must be approved (in writing, orally, or in accordance with other customary business practices), (ii) each party's rights regarding the product or the service to be transferred can be identified, (iii) the payment terms for the product or the service to be transferred can be identified, (iv) the contract must have commercial substance (that is, the risk, timing or amount of future cash flows is expected to change as a result of the contract), and (v) it is probable that the Company will collect substantially all of the consideration to which it is entitled to receive in exchange for the transfer of the product or the service.

A performance obligation is defined as a promise to transfer a product or a service to a customer. The Company identifies each promise to transfer a product or a service (or a bundle of products or services, or a series of products and services that are substantially the same and have the same pattern of transfer) that is distinct. A product or a service is distinct if both (i) the customer can benefit from the product or the service either on its own or together with other resources that are readily available to the customer and (ii) the Company's promise to transfer the product or the service to the customer is separately identifiable from other promises in the contract. Each distinct promise to transfer a product or a service is a unit of accounting for revenue recognition. If a promise to transfer a product or a service is not separately identifiable from other promises in the contract, such promises should be combined into a single performance obligation.

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The transaction price is the amount of consideration the Company is entitled to receive in exchange for the transfer of control of a product or a service to a customer. To determine the transaction price, the Company considers the existence of any significant financing component, the effects of any variable elements, noncash considerations and consideration payable to the customer. If a significant financing component exists, the transaction price is adjusted for the time value of money. If an element of variability exists, the Company must estimate the consideration it expects to receive and uses that amount as the basis for recognizing revenue as the product or the service is transferred to the customer. There are two methods for

determining the amount of variable consideration: (i) the expected value method, which is the sum of probability-weighted amounts in a range of possible consideration amounts, and (ii) the mostly likely amount method, which identifies the single most likely amount in a range of possible consideration amounts.

If a contract has multiple performance obligations, the Company allocates the transaction price to each distinct performance obligation in an amount that reflects the consideration the Company is entitled to receive in exchange for satisfying each distinct performance obligation. For each distinct performance obligation, revenue is recognized when (or as) the Company transfers control of the product or the service applicable to such performance obligation.

In those instances where the Company first receives consideration in advance of satisfying its performance obligation, the Company classifies such consideration as deferred revenue until (or as) the Company satisfies such performance obligation. In those instances where the Company first satisfies its performance obligation prior to its receipt of consideration, the consideration is recorded as accounts receivable.

The Company expenses incremental costs of obtaining and fulfilling a contract as and when incurred if the expected amortization period of the asset that would be recognized is one year or less, or if the amount of the asset is immaterial. Otherwise, such costs are capitalized as contract assets if they are incremental to the contract and amortized to expense proportionate to revenue recognition of the underlying contract.

Stock Price Appreciation Milestones

The Company estimates the fair value of the stock price appreciation milestones associated with the Amended and Restated Exclusive License Agreement with Memorial Sloan Kettering Cancer Center (MSKCC) using a Monte Carlo simulation model, which relies on the Company's current stock price as well as significant estimates and assumptions to determine the estimated liability associated with the contingent milestone payments. The Company accounts for the fair value of the stock price appreciation

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milestones in accordance with ASC 815, *Derivatives and Hedging,* with fair value marked to market at each reporting date. The assumptions used to calculate the fair value of the stock price appreciation milestones are subject to a significant amount of judgment including the probability of achieving a specified clinical milestone, the expected volatility of the Company's common stock, the risk-free interest rate, and the estimated term, which is based in part on the last valid patent claim date. The Company remeasures the fair value of the stock price appreciation milestones at each balance sheet date, with changes in fair value recorded in earnings as non-operating income or expense on the consolidated statements of operations and comprehensive loss.

Research and Development Costs

All research and development costs are expensed as incurred.

Patent Costs

Costs related to filing and pursuing patent applications are recorded as general and administrative expense and expensed as incurred since recoverability of such expenditures is uncertain.

Stock-Based Compensation

Stock-based compensation expense represents the cost of the grant date fair value of employee stock option and restricted stock unit grants recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis. Performance-based stock units/awards represent a right to receive a certain number of shares of the Company's common stock based on the achievement of corporate performance goals and continued employment during the vesting period. At each reporting period, and to the extent achievement of one or any of the performance conditions is probable, the Company reassesses the probability of the achievement of such corporate performance goals and any increase or decrease in share-based compensation expense resulting from an adjustment in the estimated shares to be released is treated as a cumulative catch-up in the period of adjustment. For stock awards for which vesting is subject to both performance-based milestones and market conditions, expense is recorded over the derived service period after the point when the achievement of the performance-based milestone is probable or the performance condition has been achieved.

The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model, with the exception of option grants for which vesting is subject to both performance-based milestones and market conditions, which are valued using a lattice-based model. The fair value of restricted stock units, including performance-based restricted stock units, is based on the closing price of the Company's common stock as reported on The Nasdaq Global Market on the date of grant. The Company recognizes forfeitures for all awards as such forfeitures occur.

Convertible Preferred Stock

The Company applies the relevant accounting standards to distinguish liabilities from equity when assessing the classification and measurement of preferred stock. Preferred shares subject to mandatory redemptions are considered liabilities and measured at fair value. Conditionally redeemable preferred shares are considered temporary equity. All other preferred shares are considered as stockholders' equity.

The Company applies the relevant accounting standards for derivatives and hedging (in addition to distinguishing liabilities from equity) when accounting for hybrid contracts that contain conversion options. Conversion options must be bifurcated from the host instruments and accounted for as free-standing financial instruments according to certain criteria. These criteria include circumstances when (i) the economic characteristics and risks of the embedded derivative instruments are not clearly and closely related to the economic characteristics and risks of the host contract, (ii) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under otherwise applicable accounting principles with changes in fair value reported in earnings as they occurred, and (iii) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument. The derivative is subsequently measured at fair value at each reporting date, with the changes in fair value reported in earnings.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

Employee Retention Credit

The CARES Act provides an employee retention credit (ERC), which is a refundable tax credit against certain employment taxes of up to $5,000 per employee for eligible employers. The tax credit is equal to 50% of qualified wages paid to employees during a quarter, capped at $10,000 of qualified wages per employee through December 31, 2020. Additional relief provisions were passed by the United States government, which extend and slightly expand the qualified wage caps on these credits through December 31, 2021. Based on these additional provisions, the tax credit is now equal to 70% of qualified wages paid to employees during a quarter, and the limit on qualified wages per employee has been increased to $10,000 of qualified wages per quarter. The Company qualifies for the tax credit under the CARES Act and expects to continue to receive additional tax credits under the additional relief provisions for qualified wages through December 31, 2021. In connection with the CARES Act, the Company adopted a policy to recognize the employee retention credit when received and include in other income in the statement of operations. Accordingly, the The Company received a cash

payment and recorded $5.1 million and $0.5 million of other income during the year ended December 31, 2022. The Company did not receive or record other income during the years ended December 31, 2021 or 2020. December 31, 2023 and 2022, respectively.

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Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. Other comprehensive loss includes unrealized gains and losses other than losses attributable to a credit loss which are included in other income and expense, on investments classified as available-for-sale securities, which was the only difference between net loss and comprehensive loss for the applicable periods. securities.

Net Loss Per Common Share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents. The Pre-Funded Warrants associated with the January 2021 public equity offering (see Note 9) are considered outstanding shares in the basic earnings per share calculation given their nominal exercise price. Dilutive common stock equivalents comprise convertible preferred stock, warrants for the purchase of common stock, and common stock options and restricted stock units outstanding under the Company's stock option plans. For all periods presented, there is no difference in the number of common shares used to calculate basic and diluted common shares outstanding due to the Company's net loss position.

Potentially dilutive securities that are not included in the calculation of diluted net loss per common share because to do so would be anti-dilutive are as follows (in common stock equivalent shares):

	As of December 31,			As of December 31,	
	2022	2021	2020	2023	2022
Common stock options	7,267,226	7,708,263	10,432,822	9,850,841	7,267,226
Restricted stock units	5,862,733	4,008,832	1,401,732	3,065,087	5,862,733
Series A convertible preferred stock (if converted)	13,972,745	13,972,745	13,972,745	13,805,540	13,972,745
Total	27,102,704	25,689,840	25,807,299	26,721,468	27,102,704

Going Concern Assessment

Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year from the financial statement issuance date. The Company determined that there are no conditions or events that raise substantial doubt about its ability to continue as a going concern for a period of at least twelve months from the date of issuance of these financial statements.

Restructuring

In January 2023, the Company implemented a corporate restructuring to streamline operations, reduce operating expenses, extend cash runway and focus resources on the Company's most promising programs. In connection with the restructuring, the Company reduced its workforce by 60%. Affected employees were informed on January 5, 2023. The restructuring was completed by March 31, 2023. The Company incurred charges of $12.9 million during the year ended December 31, 2023 for severance and other employee termination-related costs, of which $10.9 million were related to research and development expenses and $2.0 million were related to general and administrative expenses. All restructuring and related expenses have been fully recognized by the Company.

2. Collaboration and License Agreements

Janssen Ono Collaboration and Option Agreement

On April 2, 2020 (the Janssen Agreement Effective Date) September 14, 2018, the Company entered into a Collaboration and Option Agreement (the Janssen Ono Agreement) with Janssen Biotech, Inc. (Janssen) Ono Pharmaceutical Co., part Ltd. (Ono) for the joint development and

commercialization of two off-the-shelf iPSC-derived CAR T-cell product candidates (Candidate 1 and Candidate 2). Pursuant to the terms of the

Janssen Pharmaceutical Companies of Johnson & Johnson. Additionally, on the Janssen Agreement Effective Date, the Company entered into a Stock Purchase Agreement (the Stock Purchase Agreement) with JJDC.

Upon entering the Janssen Ono Agreement, the Company received an upfront, non-refundable and non-creditable payment of $50.0 10.0 million. Under the Janssen Agreement, Janssen and the Company will collaborate to develop iPSC-derived CAR NK and CAR T-cell product candidates for the treatment of cancer. Janssen will contribute proprietary antigen binding domains directed to up to four tumor-associated antigen targets (the Janssen Cancer Targets). The Company will research and construct iPSC-derived CAR NK and CAR T-cell product candidates directed to each of the Janssen Cancer Targets (the Collaboration Candidates) and perform preclinical development of Collaboration Candidates. Upon the Company's completion of activities sufficient to allow the filing of an IND application for a Collaboration Candidate, Janssen will have the right to exercise an exclusive option and obtain an exclusive license to the Company's intellectual property rights for the development and commercialization for each Collaboration Candidate. Upon the exercise of such exclusive option, Janssen will be solely responsible for the worldwide clinical development and commercialization of such Collaboration Candidate, and the Company will be primarily responsible for the manufacture, at Janssen's cost, of such Collaboration Candidate. For each Collaboration Candidate, upon attaining clinical proof-of-concept, the Company shall have the right to elect to co-commercialize and share equally in the profits and losses in the United States, subject to the Company sharing in certain development costs.

Under the terms of the Janssen Agreement, Additionally, the Company is entitled to receive full funding for all research, preclinical development and IND-enabling activities performed by the Company for Collaboration Candidates, and is eligible to receive (i) with respect to the first Janssen Cancer Target, payments of up to $898.0 million upon the achievement of specified development,

regulatory and sales milestones (the Janssen Milestone Payments) for the first Collaboration Candidate, and up to $460.0 million in Janssen Milestone Payments for each additional Collaboration Candidate, directed to the first Janssen Cancer Target; and (ii) with respect to each of the second, third and fourth Janssen Cancer Targets, up to $706.0 million in Janssen Milestone Payments for each of the first Collaboration Candidates, and up to $340.0 million in Janssen Milestone Payments for each additional Collaboration Candidate, directed to the applicable Janssen Cancer Target, where certain Janssen Milestone Payments under (i) and (ii) are subject to reduction in the event the Company elects to co-commercialize and share equally in the profits and losses in the United States of a respective Collaboration Candidate. The Company is further eligible to receive double-digit tiered royalties ranging up to the mid-teens on net sales of Collaboration Candidates that are commercialized by Janssen under the Janssen Agreement, subject to reduction under certain circumstances.

Under the Stock Purchase Agreement, the Company sold 1.6 million shares of common stock to JJDC at $31.00 per share, for an aggregate purchase price of approximately $50.0 million, on April 7, 2020. The Company determined that this common stock purchase represented a premium of $9.93 per share, or $16.0 million in aggregate (the Equity Premium), and the remaining $34.0 million was recorded as an issuance of common stock in shareholders' equity.

In addition, under the Stock Purchase Agreement, the Company had the right to require JJDC to purchase an aggregate of $50.0 million in shares of the Company's common stock in a private placement at the same price per share as that paid by investors in a public offering. In June 2020, in connection with the Company's June 2020 public offering, the Company exercised this right and JJDC purchased in a private placement 1.8 million shares of the Company's common stock at a price of $28.31 per share, for aggregate proceeds of $50.0 million.

The Janssen Agreement permits Janssen to terminate development with respect to one or more Janssen Cancer Targets, or the entire Janssen Agreement, at any time on or after the second anniversary of the Janssen Agreement Effective Date, and the Company may terminate the Janssen Agreement with respect to a particular Janssen Cancer Target if a Collaboration Candidate has not been selected for IND-enabling studies for such Janssen Cancer Target within specified time periods under certain conditions. The Janssen Agreement contains customary provisions for termination by either party in the event of a material breach of the Janssen Agreement, subject to cure, by the other party and in the event of any bankruptcy, insolvency or similar events with respect to the other party.

The Company applied ASC Topic 808, *Collaborative Arrangements* (ASC 808) and determined the Janssen Agreement is applicable to such guidance. The Company concluded that certain units of account within the Janssen Agreement represented a customer relationship and applied relevant guidance from ASC Topic 606, *Revenue from Contracts with Customers* (ASC 606) to evaluate the appropriate accounting for the Janssen Agreement. In accordance with this guidance, the Company identified its potential performance obligations, including its grant of a license to Janssen to certain of its intellectual property subject to certain conditions, its conduct of research and development services, and its participation in various joint oversight committees. The Company determined that its grant of a license to Janssen to certain of its intellectual property in the initial development stage was not distinct from other performance obligations because such grant is dependent on the conduct and results of the research and development services. Accordingly, the Company determined that its grant of a license to Janssen and its conduct of research and development services should be accounted for as one combined performance obligation, and that the combined performance obligation is transferred over the expected term of the conduct of the research and development services, which is estimated to be four years. Additionally, the Company determined that participation in the various joint oversight committees did not constitute a performance obligation as the Company's participation in the various joint

oversight committees does not transfer a service.

The Company also assessed the effects of any variable elements under the Janssen Agreement. Such assessment evaluated, among other things, the funding to be received by the Company for its conduct of research and development services. Based on its assessment, the Company concluded that the total amount to be received by the Company for its conduct of research and development services is variable and cannot be readily estimated and, therefore, no amounts associated with such services were included in the initial transaction price. In addition, the Company also assessed its likelihood of receiving (i) preclinical milestones, (ii) various clinical, regulatory and commercial milestone payments, and (iii) royalties on net sales of the Collaboration Candidates. Based on the likelihood of receiving such milestone payments and royalties, no amounts associated with milestones or royalties were included in the initial transaction price.

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In accordance with ASC 606, the Company determined that the initial transaction price under the Janssen Agreement equals $66.0 million, consisting of the upfront, non-refundable and non-creditable payment of $50.0 million and the Equity Premium of $16.0 million. The Company concluded that there was not a significant financing component under the Janssen Agreement. The upfront payment of $66.0 million was recorded as deferred revenue and is being recognized as revenue consistent with the Company's efforts related to the conduct of research and development services, as the research and development services are the primary component of the combined performance obligation. Since the total amount to be received by the Company for its research and development services under the Janssen Agreement could not be readily estimated, revenue associated with the upfront payment will be recognized based on actual headcount utilized as a percentage of total headcount expected to be utilized over the expected term of the conduct of the research and development services. Revenue associated with the research and development services will be recognized in an amount equal to the actual costs incurred during the period in which the research and development services are performed by the Company.

During the year ended December 31, 2022, the Company achieved two research milestones under the Janssen Agreement and received a cash payment of $3.0 million each, for a total of $6.0 million received. In accordance with ASC 606, the Company determined that the milestone receivables represented an increase in the initial transaction price under the Janssen Agreement in the form of the receipt of variable consideration that was previously constrained. The Company recognized revenue associated with the milestone receivables in an amount equal to the proportional percentage of actual headcount incurred under the Janssen Agreement since its inception as a percentage of the total headcount expected to be utilized over the expected term of conduct of research and development services under the Janssen Agreement. The remaining unrecognized revenue associated with the milestones was recorded to deferred revenue, and is being recognized as revenue over the expected term of conduct of research and development services.

On May 26, 2022, Janssen exercised a commercial option for a development candidate with respect to a particular Janssen Antigen (as defined under the Janssen Agreement). As a result, the Company received an Option Exercise Payment (as defined under the Janssen Agreement) of $10.0 million under the Janssen Agreement. The Company determined the exercise represented an option with no material right under the Janssen Agreement. The Company has not completed its performance obligations with respect to the exercise of the commercial option and accordingly, the Company has not recognized any revenue associated with the option exercise for the year ended December 31, 2022. The cash received for the Option Exercise Payment was recorded to deferred revenue, and will be recognized as revenue upon completion of the performance obligations.

On September 14, 2022, Janssen provided notice of their intent to exercise a second commercial option for a development candidate with respect to a particular Janssen Antigen (as defined under the Janssen Agreement). This option exercise is subject to Competition Law Filings, and therefore the exercise effective date was deemed to be the Clearance Date, which occurred during the year ended December 31, 2022. Janssen owes the Company an Option Exercise Payment (as defined under the Janssen Agreement) of $10.0 million under the Janssen Agreement. The Company determined the exercise represented an option with no material right under the Janssen Agreement. The Company has completed its performance obligations with respect to the exercise of the commercial option and accordingly, recognized the Option Exercise Payment as revenue for the year ended December 31, 2022.

On November 18, 2022, the Company filed an IND for the second antigen, development candidate, which was cleared by the FDA during the year ended December 31, 2022. Accordingly, the Company achieved a $3.0 million pre-defined clinical development milestone under the Janssen Agreement which was recognized as revenue during the year ended December 31, 2022.

As a direct result of the Company's entry into the Janssen Agreement, the Company incurred $17.1 million in sublicense fees to certain of its existing licensors. The $17.1 million in sublicense consideration represents an asset under ASC 340, *Other Assets and Deferred Costs* (ASC 340) and is amortized to research and development expense ratably with the Company's revenue recognition under the Janssen Agreement. During the years ended December 31, 2022 and 2021, the Company recognized $4.3 million and $1.7 million of such expense, respectively. As of December 31, 2022, the Janssen Agreement contract asset balance was $7.2 million.

The Company recognized revenue of $79.7 million under the Janssen Agreement for the year ended December 31, 2022. Such revenue comprised $42.3 million associated with research and development services, $23.1 million associated with the upfront fee and Equity Premium, $13.0 million associated with a commercial option exercise and milestone achievements, and $1.3 million associated with collaboration services for the year

ended December 31, 2022. The Company recognized revenue of $43.7 million under the Janssen Agreement for the year ended December 31, 2021.

Such revenue comprised $29.5 million associated with research and development services and $14.2 million associated with the upfront fee and Equity Premium for the year ended December 31, 2021. As of December 31, 2022, aggregate deferred revenue related to the Janssen Agreement was $41.2 million, all of which is classified as current.

As of December 31, 2022, the Company has received $70.4 million in cash in aggregate research and development fees from Janssen.

On January 3, 2023, the Company received notice of termination from Janssen of the Janssen Agreement. The termination will take effect on April 3, 2023 and, during the first quarter of 2023, the Company will wind down activities with Janssen, including discontinuing development of all collaboration products. Under the terms of the Janssen Agreement, in connection with the

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termination, (i) all licenses and other rights granted to either party pursuant to the Janssen Agreement will terminate, subject to limited exceptions set forth in the Janssen Agreement; (ii) both parties will wind down any development, commercialization and manufacturing activities under the Janssen Agreement; (iii) neither party will have any right to continue to develop, manufacture or commercialize any collaboration candidate or collaboration product or use the other party's materials; and (iv) neither party is restricted from independently developing, manufacturing, or commercializing any product, including any products directed to the same antigens as those of any collaboration candidate or collaboration product.

Ono Collaboration and Option Agreement

Under a collaboration and option agreement with Ono Pharmaceutical Co. Ltd. (Ono) entered into in September 2018 and amended in June 2022 (the Ono Agreement), the Company is conducting research and preclinical development of off-the-shelf, iPSC-derived, CAR-targeted effector cells for the treatment of solid tumors.

The Ono Agreement was initially designed to research and preclinically develop two iPSC-derived CAR T-cell product candidates, one of which was designated to target an antigen expressed on certain lymphoblastic leukemias (Candidate 1) and the second of which was designated to target an antigen expressed on certain solid tumors (Candidate 2) (each a Candidate and, collectively, the Candidates). The Company granted to Ono, during a specified period of time, a preclinical option to obtain an exclusive license under certain intellectual property rights to develop and commercialize: (a) Candidate 1 in Asia, where the Company retained rights for development and commercialization in all other territories of the world; and (b) Candidate 2 in all territories of the world, where the Company retained rights to co-develop and co-commercialize Candidate 2 in the United States and Europe under a joint arrangement with Ono under which the Company is eligible to share at least 50% of the profits and losses. The Company maintained worldwide rights of manufacture for each Candidate. For each Candidate, the preclinical option expired upon the earliest of: (a) the achievement of the pre-defined preclinical milestone under the joint development plan; (b) termination by Ono of research and development activities for the Candidate; and (c) the date that is the later of (i) four years after the effective date, and (ii) completion of all applicable activities contemplated under the joint development plan. Ono paid the Company an upfront, non-refundable and non-creditable payment of $10.0 million in connection with entering into the Ono Agreement. Additionally, as consideration for the conduct of research and preclinical development under a joint development plan, Ono agreed to pay the Company annual research and development fees set forth in the annual budget included in the joint development plan, which fees were estimated to be $20.0 million in aggregate over the course of the joint development plan.aggregate.

In December 2020, the Company entered into a letter agreement with Ono pursuant to which Ono delivered proprietary antigen binding domains targeting an antigen expressed on certain solid tumors for incorporation into Candidate 2 and paid the Company a milestone fee of $10.0 million for further research and development of Candidate 2. In addition, Ono terminated all further research

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and development with respect to Candidate 1, and the Company retained all rights to research, develop and commercialize Candidate 1 throughout the world without any obligation to Ono.

In June 2022, the Company entered into an amendment with Ono to the Ono Agreement (the 2022 Ono Amendment). Pursuant to the 2022 Ono Amendment, the companies agreed to designate an additional antigen expressed on certain solid tumors for research and preclinical development, and Ono agreed to contribute proprietary antigen binding domains targeting such additional solid tumor antigen (Candidate 3). In addition, for both Candidate 2 and Candidate 3, Ono and the companies Company expanded the scope of the collaboration to include the research and development of iPSC-derived CAR NK cell product candidates (in addition to iPSC-derived CAR T-cell product candidates) targeting the designated solid tumor

antigens. Similar to Candidate 2, the Company granted to Ono, during a specified period of time, a preclinical option to obtain an exclusive license

under certain intellectual property rights, subject to payment of an option exercise fee to the Company by Ono, to develop and commercialize Candidate 3 in all territories of the world, where the Company retains rights to co-develop and co-commercialize Candidate 3 in the United States and Europe under a joint arrangement with Ono under which the Company is eligible to share at least 50% of the profits and losses. The Company will continue to receive committed funding from Ono through September 2024 and has maintained worldwide rights of manufacture for Candidate 3. The preclinical option expires upon the earlier of: (a) September 30, 2024, or (b) the achievement of the pre-defined preclinical milestone under the joint development plan for Candidate 3. Subject to payment of an extension fee by Ono, Ono may choose to defer its decision to exercise the preclinical option until no later than June 2026. Under the 2022 Ono Amendment, aggregate estimated research and development fees have been increased by approximately $9.3 million, for a total estimated $29.3 million in aggregate research and development fees over the course of the joint development plan.

On November 7, 2022, Ono exercised its option for continued development of Candidate 2. Upon Ono's exercise, the Company granted Ono a license to develop and commercialize Candidate 2. The Company elected its preclinical option to co-develop and co-commercialize Candidate 2. As a result, the Company received an Option Exercise Payment (as defined under the Ono Agreement) of $12.5 million. The Company determined the exercise represented an option with no material right under the Ono Agreement. The Company has completed its performance obligations with respect to the exercise of the option and accordingly, recognized the Option Exercise Payment as revenue for the year ended December 31, 2022. The Company and Ono will proceed with a joint development plan for the ongoing development of Candidate 2. The costs of this development plan are accounted for in accordance with ASC 808, and cost sharing payments to the Company from Ono are recorded net into research and development expenses. During the year ended December 31, 2023, the Company recognized contra-research and development expense of $8.0 million. There were no such amounts recognized during the year ended December 31, 2022 As of December 31, 2023, the Company has received $6.2 million in aggregate cost-sharing payments from Ono.

On November 30, 2023, the Company entered into an amendment with Ono to the Ono Agreement (the 2023 Ono Amendment). Under the 2023 Ono Amendment, aggregate estimated research and development fees have been increased by approximately $1.4 million, for a total estimated $30.7 million in aggregate research and development fees over the course of the joint development plan.

Under the terms of the Ono Agreement (as amended by the 2022 Ono Amendment), for Candidate 2 and for Candidate 3 (subject to exercise by Ono of its preclinical option to Candidate 3), we are the Company is eligible to receive additional payments upon the achievement of certain clinical, regulatory and commercial milestones (the Ono Milestones) with respect to each Candidate in an amount up to $843.0 million in aggregate, with the applicable milestone payments for the United States and Europe subject to reduction by 50% if we elect the Company elects to co-develop and co-commercialize the Candidate in the United States and Europe as described above. In addition, in those territories where Ono has exclusive rights of commercialization, we are the Company is eligible to receive tiered royalties (Royalties) ranging from the mid-single digits to the low-double digits based on annual net sales by Ono for each Candidate in such territories, with such royalties the Royalties subject to certain reductions.

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The Ono Agreement will terminate with respect to a Candidate if Ono does not exercise its option for a Candidate candidate within the option period, or in its entirety if Ono does not exercise any of its options for the Candidates candidates within their respective option periods. In addition, either party may terminate the Ono Agreement in the event of breach, insolvency or patent challenges by the other party; provided, that Ono may terminate the Ono Agreement in its sole discretion (x) on a Candidate-by-Candidate basis at any time after the second anniversary of the effective date of the Ono Agreement or (y) on a Candidate-by-Candidate or country-by-country basis at any time after the expiration of the option period, subject to certain limitations. The Ono Agreement will expire on a Candidate-by-Candidate and country-by-country basis upon the expiration of the applicable royalty Royalty term, or in its entirety upon the expiration of all applicable payment obligations under the agreement.

The Company determined that the Ono Agreement, Ono Letter Agreement, and Ono Amendment Amendments were within the scope of ASC 808. 808 and applicable to such guidance. The Company concluded that certain units of account within the Ono Agreement and Ono Amendment Amendments represented a customer and applied relevant guidance from ASC 606 to evaluate the appropriate accounting for the those units of account. In accordance with this guidance, the Company identified its performance obligations, including its grant of a license to Ono to certain of its intellectual property subject to certain conditions, its conduct of research services, and its participation in a joint steering committee. The Company determined that its grant of a license to Ono to certain of its intellectual property subject to certain conditions was not distinct from other performance obligations because such grant is dependent on the conduct and results of

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the research services. Additionally, the Company determined that its conduct of research services was not distinct from other performance obligations since such conduct is dependent on the guidance of the joint steering committee. Accordingly, the Company determined that all performance obligations should be accounted for as one combined performance obligation, and that the combined performance obligation is transferred over the expected term of the conduct of the research services, which is estimated to be four years. services. The termination of the Ono Agreement with respect to Candidate 1 did not impact this assessment.

The Company also assessed, in connection with the upfront, non-refundable and non-creditable payment of $10.0 million received in September 2018 and the $5.0 million prepayment of the first-year research and development fees in October 2018, and concluded that there was not a significant financing component to the Ono Agreement.

The Company also assessed the effects of any variable elements under the Ono Agreement and Ono Amendment. Such assessment evaluated, among other things, the likelihood of receiving (i) preclinical milestone and option fees, (ii) various clinical, regulatory and commercial milestone payments, and (iii) royalties on net sales of either product Candidate. Based on its assessment, the Company concluded that, based on the likelihood of these variable components occurring, there was not a significant variable element included in the transaction price. Accordingly, the Company has not assigned a transaction price to any Ono Option Milestone, Ono Milestones or Ono Option Exercise Fees, other than the $10.0 million milestone triggered as part of the Ono Letter Agreement in December 2020, given the substantial uncertainty related to their achievement and has not assigned a transaction price to any Ono Royalties.

In accordance with ASC 606, the Company determined that the initial transaction price under the 2023 Ono Agreement equals Amendment equaled $39.3 40.7 million, consisting of the upfront, non-refundable and non-creditable payment of $10.0 million and the aggregate estimated research and development fees of $29.3 30.7 million. The upfront payment of $10.0 million was recorded as deferred revenue and is being was recognized as revenue over time in conjunction with the Company's conduct of research services as the research services are the primary component of the combined performance obligations. Revenue associated with the upfront payment will be was recognized based on actual costs incurred as a percentage of the estimated total costs expected to be incurred over the expected term of conduct of the research services. The Company recorded the $5.0 million prepayment of the first-year research and development fees as deferred revenue, and such fees were recognized as revenue as the research services were delivered.

In accordance with ASC 606, the Company concluded that the $10.0 million milestone payment associated with the Ono Letter Agreement represented an increase in the initial transaction price under the Ono Agreement in the form of the receipt of variable consideration that was previously constrained. The Company recognized revenue associated with the $10.0 million milestone payment in an amount equal to the proportional percentage of actual costs incurred under the Ono Agreement as a percentage of the estimated total costs expected to be incurred over the expected term of conduct of the research services.

On November 7, 2022, Ono exercised its option for continued development of Collaboration Candidate 2 (as defined under the Ono Agreement). Upon exercise, the Company granted Ono a license to develop and commercialize Collaboration Candidate 2. The Company elected its CDCC Option for Collaboration Candidate 2. As a result, the Company is owed an Option Exercise Payment (as defined under the Ono Agreement) of $12.5 million. The Company determined the exercise represented an option with no material right under the Ono Agreement. The Company has completed its performance obligations with respect to the exercise of the option and accordingly, recognized the Option Exercise Payment as revenue for the year ended December 31, 2022. The Company and Ono will establish a joint development plan for the ongoing development of Collaboration Candidate 2. The costs of this development plan are accounted for in accordance with ASC 808, and cost sharing payments to the Company from Ono are recorded net into research and development expenses. As of December 31, 2022, there were no cost-sharing payments made to the Company from Ono.

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As a direct result of the Company's entry into the Ono Agreement and the Ono Letter Agreement, the Company incurred an aggregate of $7.8 million in sublicense consideration to existing licensors of the Company. The $7.8 million in sublicense consideration represents an asset under ASC 340 and is being amortized to research and development expense ratably with the Company's revenue recognition under the Ono Agreement. During the years ended December 31, 2022 and 2021, , the Company recognized $4.1 million and $1.2 million, respectively, of such expense. As of December 31, 2022 During the year ended December 31, 2023, there is the Company recognized no remaining contract asset balance for the Ono Agreement. such expense.

The Company recognized revenue of $16.6 million, $12.1 11.2 million and $14.6 16.6 million under the Ono Agreement and Ono Letter Agreement during the years ended December 31, 2022, 2021 December 31, 2023 and 2020, 2022, respectively. Such revenue comprised $11.2 million associated with research services during the year ended December 31, 2023. Such revenue comprised $2.5 million associated with research services and $1.6 million associated with the upfront payment, and $12.5 million associated with the option exercise during the year ended December 31, 2022. Such revenue comprised $6.0 million associated with the Ono Letter Agreement milestone earned in December 2021, $6.0 million associated with research services and $6.1 million associated with the upfront payment during the year ended December 31, 2021. Such revenue comprised $5.7 million associated with research services and $2.8 million associated with the upfront payment during the year ended December 31, 2020. As of

December 31, 2022 December 31, 2023, aggregate deferred revenue related to the Ono Agreement and Ono Letter Agreement was $1.1 0.7 million, all of which is classified as current.

As of December 31, 2022 December 31, 2023, the Company has received $21.9 32.7 million in cash of aggregate research and development fees from Ono.

Janssen Collaboration and Option Agreement

On April 2, 2020 (the Janssen Agreement Effective Date), the Company entered into a Collaboration and Option Agreement (the Janssen Agreement) with Janssen Biotech, Inc. (Janssen), part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Additionally, on the Janssen Agreement Effective Date, the Company entered into a Stock Purchase Agreement (the Stock Purchase Agreement) with Johnson & Johnson Innovation - JJDC, Inc. (JJDC). On January 3, 2023, the Company received notice of termination from Janssen of the Janssen Agreement. The termination took effect on April 3, 2023, and during the three months ended March 31, 2023, the Company performed wind-down activities including discontinuing development of all collaboration product candidates under the Janssen Agreement. The Company was reimbursed for all wind-down activities.

Under the terms of the Janssen Agreement and the Stock Purchase Agreement taken together, the Company received $100.0 million, of which $50.0 million was an upfront cash payment and $50.0 million was in the form of an equity investment by JJDC. The Company determined the common stock purchase by JJDC represented a premium of $9.93 per share, or $16.0 million in aggregate (the Equity Premium), and the remaining $34.0 million was recorded as issuance of common stock in shareholders' equity. In addition, under the Stock Purchase Agreement, the Company exercised the right to require JJDC to purchase an aggregate of $50.0 million in shares in a private placement at the same price per share as paid by investors in a public offering. In June 2020, JJDC purchased 1.8 million shares of the Company's common stock at a price of $28.31 per share. Additionally, the Company received full funding for the conduct of all research, preclinical development and Investigational New Drug Application (IND)-enabling activities performed by the Company under the Janssen Agreement.

As a direct result of the Company's entry into the Janssen Agreement, the Company incurred $17.1 million in sublicense fees to certain of its existing licensors. The $17.1 million in sublicense consideration represents an asset under ASC 340, *Other Assets and Deferred Costs* (ASC 340) and is amortized to research and development expense ratably with the Company's revenue recognition under the Janssen Agreement. During the years ended December 31, 2023 and 2022, the Company recognized $7.2 million and $4.3 million of such expense, respectively. As of December 31, 2023, there was no remaining balance on the Janssen Agreement contract asset.

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The Company recognized revenue of $52.3 million under the Janssen Agreement for the year ended December 31, 2023, of which $41.2 million was previously deferred. Such revenue comprised $11.1 million associated with research and development services, $31.2 million associated with the upfront fee and Equity Premium, and $10.0 million associated with a commercial option exercise for the year ended December 31, 2023. The Company recognized revenue of $79.7 million under the Janssen Agreement for the year ended December 31, 2022. Such revenue comprised $42.3 million associated with research and development services and $23.1 million associated with the upfront fee and Equity Premium, $13.0 million associated with a commercial option exercise and milestone achievements, and $1.3 million associated with collaboration services for the year ended December 31, 2022.

Memorial Sloan Kettering Cancer Center License Agreement

On May 15, 2018, the Company entered into an Amended and Restated Exclusive License Agreement (the Amended MSK MSKCC License) with Memorial Sloan Kettering Cancer Center (MSK). MSKCC. The Amended MSK MSKCC License amends and restates the Exclusive License Agreement entered into between the Company and MSK MSKCC on August 19, 2016 (the Original MSK MSKCC License), pursuant to which the Company entered into an exclusive license agreement with MSK MSKCC for rights relating to compositions and methods covering iPSC-derived cellular immunotherapy, including T-cells and NK-cells derived from iPSCs engineered with CARs.

Pursuant to the Amended MSK MSKCC License, MSK MSKCC granted to the Company additional licenses to certain patents and patent applications relating to new CAR constructs and off-the-shelf CAR T cells, T-cells, including the use of clustered regularly interspaced short palindromic repeat (CRISPR) and other innovative technologies for their production, in each case to research, develop, and commercialize licensed products in the field of all human therapeutic uses worldwide. The Company has the right to grant sublicenses to certain licensed rights in accordance with the terms of the Amended MSK MSKCC License, in which case it is obligated to pay MSK MSKCC a percentage of certain sublicense income received by the Company.

Company.

The Company is obligated to pay to MSK MSKCC an annual license maintenance fee during the term of the agreement, and milestone payments upon the achievement of specified clinical, regulatory and commercial milestones for licensed products as well as royalty payments on net sales of licensed products products.

In the event a licensed product achieves a specified clinical milestone, MSK MSKCC is then eligible to receive certain milestone payments totaling up to $75.0 million based on the price of the Company's common stock, where the amount of such payments owed to MSK MSKCC is contingent upon certain increases in the price of the Company's common stock following the date of achievement of such clinical milestone. These payments are based on common stock price multiples, with the numerator being the fair value of the ten-trading day trailing average closing price of the Company's common stock and the denominator being the ten-trading day trailing average closing price of the Company's common stock as of the effective date of the Amended MSK MSKCC License, adjusted for any stock splits, cash dividends, stock dividends, other distributions, combinations, recapitalizations, or similar events. Under the terms of the Amended MSK MSKCC License, upon a change of control of the Company, in certain circumstances, the Company may be required to pay a portion of these payments to MSK MSKCC based on the price of the Company's common stock in connection with such change of control.

The following table summarizes the common stock multiples and the stock price appreciation milestone payments under the terms of the agreement:

Common stock multiple	5.0x	10.0x	15.0x
Ten-trading day trailing average common stock price	$ 50.18	$ 100.36	$ 150.54
Stock price appreciation milestone payment (in millions)	$ 20.0	$ 30.0	$ 25.0

In July 2021, the Company achieved the specified clinical milestone for a licensed product under the Amended MSK MSKCC License and the Company's ten-trading day trailing average common stock price exceeded the first, pre-specified threshold. As a result, the Company remitted the first milestone payment of $20.0 million to MSK MSKCC during the year ended December 31, 2021.

To determine the estimated fair value of the remaining stock price appreciation milestones, the Company uses a Monte Carlo simulation methodology which models future Company common stock prices based on the current stock price and several key

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variables. The following variables were incorporated in the calculation of the estimated fair value of the stock price appreciation milestones as of December 31, 2022 December 31, 2023:

	Year Ended December 31, 2022	Year Ended December 31, 2021
Risk-free interest rate	4.0%	1.7%
Expected volatility	78.1%	77.6%
Estimated term (in years)	16.0	17.0
Closing stock price as of measurement date	$ 10.09	$ 58.51

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	Year Ended December 31, 2023	Year Ended December 31, 2022
Risk-free interest rate	4.0%	4.0%
Expected volatility	84.0%	78.1%
Estimated term (in years)	15.0	16.0
Closing stock price as of measurement date	$ 3.74	$ 10.09

The key inputs to the Monte Carlo simulation to determine the fair value of the stock price appreciation milestones include the Company's stock price as of the measurement date; the estimated term which is based in part on the last valid patent claim date; the expected volatility of the Company's common stock, estimated using the Company's historical common stock volatility as of the remeasurement date; and the risk-free rate based on the U.S. Treasury yield for the estimated term determined. Fair value measurements are highly sensitive to changes in these inputs and significant changes could result in a significantly higher or lower fair value and resulting expense or gain.

At each balance sheet date, the Company remeasures the fair value of the stock price appreciation milestones, with changes in fair value recognized as a component of other income (expense) in the consolidated statements of operations and comprehensive loss. Amounts are included in current or non-current liabilities based on the estimated timeline associated with the individual potential payments. During the year years ended December 31, 2022 December 31, 2023 and 2021, 2022, the Company recorded $20.3 2.5 million of income and $3.5 20.3 million of income, respectively, associated with the change in fair value of the stock price appreciation milestones. During the year ended December 31, 2020, the Company recorded $47.7 million of expense. As of December 31, 2022 December 31, 2023 and 2021, 2022, the Company recorded a liability of $3.9 1.3 million and $24.2 3.9 million, respectively, associated with the stock price appreciation milestones for the Amended MSK MSKCC License.

3. California Institute for Regenerative Medicine Award

On April 5, 2018, the Company executed an award agreement with the California Institute for Regenerative Medicine (CIRM) pursuant to which CIRM awarded the Company $4.0 million to advance the Company's FT516 product candidate into a first-in-human clinical trial for the treatment of subjects with advanced solid tumors, including in combination with monoclonal antibody therapy (the Award). The Award is subject to certain co-funding requirements by the Company, and the Company is required to provide CIRM progress and financial update reports under the Award.

Pursuant to the terms of the Award, the Company, in its sole discretion, has the option to treat the Award either as a loan or as a grant. In During the event first quarter of 2023, the Company elects elected to treat the Award as a loan, grant and derecognized the Company will be obligated to repay i) 60%, ii) 80%, iii) 100% or iv) 100% plus interest at 7% plus LIBOR, of the total Award to CIRM, where such repayment rate is dependent upon the phase of clinical development of FT516 at the time of the Company's election. If the Company does not elect to treat liability associated with the Award as a loan within 10 years of and recorded such amount in other income during the date of the Award, the Award will be considered a grant and the Company will be obligated to pay to CIRM a royalty on commercial sales of FT516 until such royalty payments equal nine times the total amount awarded to the Company under the Award.

Since the Company may, at its election, repay some or all of the Award, the Company accounts for the Award as a liability until the time of election. As of December 31, 2022, the Company has received all disbursements available under the Award in the amount of $4.0 million. The aggregate amount received is recorded as a CIRM Liability on the accompanying consolidated balance sheets and classified as current based on the potential amount payable within twelve months of the current balance sheet date. year ended December 31, 2023.

4. Investments

The Company invests portions of excess cash in United States treasuries, commercial paper, non-U.S. government securities, municipal securities, and corporate debt securities with maturities ranging from three to thirty-six months from the purchase date. These investments are accounted for as available-for-sale securities and are classified as short-term and long-term investments in the accompanying consolidated balance sheets based on each security's contractual maturity date.

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The following table summarizes the Company's investments accounted for as available-for-sale securities as of December 31, 2022 December 31, 2023 and 2021 2022 (in thousands):

	Maturity (in years)	Amortized Cost	Unrealized Losses	Unrealized Gains	Estimated Fair Value
December 31, 2023					
Classified as current assets:					

Money market fund					1 or less	$ 35,273	$ —	$ —	$ 35,273
U.S. Treasury debt securities					1 or less	82,811	(34)	27	82,804
Non-US government securities					1 or less	999	—	—	999
Municipal securities					1 or less	5,000	(3)	—	4,997
Corporate debt securities					1 or less	47,144	(51)	14	47,107
Commercial paper					1 or less	137,339	(62)	121	137,398
Total short-term investments						$ 308,566	$ (150)	$ 162	$ 308,578
Classified as non-current assets:									
Corporate debt securities					Greater than 1	$ 977	$ —	$ 3	$ 980
Total long-term investments						$ 977	$ —	$ 3	$ 980

	Maturity (in years)	Amortized Cost	Unrealized Losses	Unrealized Gains	Estimated Fair Value				
December 31, 2022									
Classified as current assets:									
Money market fund						1 or less	$ 37,645	$ —	$ —	$ 37,645
U.S. Treasury debt securities	1 or less	$ 1	$ (263)	$ 37	$ 5	1 or less	86,221	(263)	37	85,995
Non-US government securities	1 or less	2,425	(2)	—	2,423	1 or less	2,425	(2)	—	2,423
Municipal securities	1 or less	18,963	(208)	—	18,755	1 or less	18,963	(208)	—	18,755
Corporate debt securities	1 or less	123,961	(1,138)	3	122,826	1 or less	126,691	(1,138)	5	125,558
Commercial paper	1 or less	152,056	(230)	4	151,830	1 or less	152,056	(230)	4	151,830
Total short-term investments		$ 376,691	$ (1,841)	$ 44	$ 374,894		$ 424,001	$ (1,841)	$ 46	$ 422,206
Classified as non-current assets:									
Municipal securities	Greater than 1	$ 5,000	$ (58)	$ —	$ 4,942	Greater than 1	$ 5,000	$ (58)	$ —	$ 4,942
Total long-term investments		$ 5,000	$ (58)	$ —	$ 4,942		$ 5,000	$ (58)	$ —	$ 4,942
December 31, 2021									
Classified as current assets:									
U.S. Treasury debt securities	1 or less	$ 3	$ (163)	$ —	$ 0					
Municipal securities	1 or less	18,017	(6)	1	18,012					
Corporate debt securities	1 or less	169,736	(187)	—	169,549					

Commercial paper	1 or	224,3			224,2
	less	33	(59)	2	76
Total short-term investments		482,7			482,3
		$ 39	$ (415)	$ 3	$ 27
Classified as non-current assets:					
U.S. Treasury debt securities	Greater				
	than 1	$ 9,989	$ (35)	$ —	$ 9,954
Municipal securities	Greater				
	than 1	9,034	(42)	—	8,992
Corporate debt securities	Greater	81,98			81,71
	than 1	9	(271)	—	8
Total long-term investments		101,0			100,6
		$ 12	$ (348)	$ —	$ 64

As of December 31, 2022 December 31, 2023 and 2021, 2022, the Company had $0.8 0.9 million and $1.1 0.8 million, respectively, of accrued interest on investments recorded in prepaid expenses and other assets on the consolidated balance sheets.

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The following tables present gross unrealized losses and fair values for those investments that were in an unrealized loss position as of December 31, 2022 and December 31, 2021, aggregated by investment category and the length of time that individual securities have been in a continuous loss position (in thousands):

	Less Than 12 Months		12 Months or Greater		Total	
	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses
December 31, 2022						
U.S. Treasury debt securities	$ 51,246	$ (163)	$ 9,898	$ (100)	$ 61,144	$ (263)
Non-US government securities	2,424	(2)	—	—	2,424	(2)
Municipal securities	14,765	(193)	8,933	(73)	23,698	(266)
Corporate debt securities	45,621	(174)	71,625	(964)	117,246	(1,138)
Commercial paper	66,455	(230)	—	—	66,455	(230)
Total	$ 180,511	$ (762)	$ 90,456	$ (1,137)	$ 270,967	$ (1,899)
December 31, 2021						
U.S. Treasury debt securities	$ 80,444	$ (198)	$ —	$ —	$ 80,444	$ (198)
Municipal securities	23,352	(48)	—	—	23,352	(48)
Corporate debt securities	250,467	(458)	—	—	250,467	(458)
Commercial paper	59,863	(59)	—	—	59,863	(59)
Total	$ 414,126	$ (763)	$ —	$ —	$ 414,126	$ (763)

The Company reviews its investment holdings at the end of each reporting period and evaluates any unrealized losses using the expected credit loss model to determine if the unrealized loss is a result of a credit loss or other factors. The Company also evaluates its investment holdings for impairment using a variety of factors including the Company's intent to sell the underlying securities prior to maturity and whether it is more likely than not that the Company would be required to sell the securities before the recovery of their amortized basis. During the years ended December 31, 2022, 2021 December 31, 2023 and 2020, 2022, the Company did not recognize any impairment or realized gains or losses on sales of investments, and the Company did not record an allowance for, or recognize, any expected credit losses.

5. Fair Value Measurements

The following tables presents the Company's financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2022 December 31, 2023 and 2021 2022 (in thousands):

		Fair Value Measurements at Reporting Date Using				Fair Value Measurements at Reporting Date Using			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
As of December 31, 2022:								
As of December 31, 2023:								
Financial assets:								
Money market funds	61,3 $ 33	61,33 $ 3	$ —	$ —				
Money market fund					$ 35,273	$ 35,273	$ —	$ —
U.S. Treasury debt securities	79,0 25	79,02 5	—	—	82,804	82,804	—	—
Non-US government securities	2,42 3	—	2,42 3	—	999	—	999	—
Municipal securities	23,6 97	—	23,6 97	—	4,997	—	4,997	—
Corporate debt securities	122, 861	—	122, 861	—	48,087	—	48,087	—
Commercial paper	151, 830	—	151, 830	—	137,398	—	137,398	—
Total assets measured at fair value on a recurring basis	441, $ 169	140,3 $ 58	300, $ 811	$ —	$ 309,558	$ 118,077	$ 191,481	$ —
Financial liabilities:								
Stock price appreciation milestones	3,86 $ 1	—	$ —	3,86 $ 1	$ 1,346	$ —	$ —	$ 1,346
Total financial liabilities measured at fair value on a recurring basis	3,86 $ 1	—	$ —	3,86 $ 1	$ 1,346	$ —	$ —	$ 1,346
As of December 31, 2021:								
As of December 31, 2022:								
Financial assets:								
Money market funds	133, $ 583	133,5 $ 83	$ —	$ —				
Money market fund					$ 37,645	$ 37,645	$ —	$ —
U.S. Treasury debt securities	80,4 44	80,44 4	—	—	85,995	85,995	—	—
Non-US government securities					2,423	—	2,423	—
Municipal securities	27,0		27,0					

Municipal securities	27,004	—	27,004	—	23,697	—	23,697	—
Corporate debt securities	251,267	—	251,267	—	125,558	—	125,558	—
Commercial paper	224,276	—	224,276	—	151,830	—	151,830	—
Total assets measured at fair value on a recurring basis	716,574	214,027	502,547	—	$ 427,148	$ 123,640	$ 303,508	$ —
Financial liabilities:								
Stock price appreciation milestones	24,168			24,168				
	$ 68	$ —	$ —	$ 68	$ 3,861	$ —	$ —	$ 3,861
Total financial liabilities measured at fair value on a recurring basis	24,168			24,168				
	$ 68	$ —	$ —	$ 68	$ 3,861	$ —	$ —	$ 3,861

Level 1 assets consisted of money market funds and U.S. Treasury securities measured at fair value based on quoted prices in active markets as provided by the Company's investment managers.

Level 2 assets consisted of corporate debt securities, commercial paper, municipal securities, and non-U.S. government securities measured at fair value using standard observable inputs, including reported trades, broker/dealer quotes, and bids and/or offers. The Company validates the quoted market prices provided by its investment managers by comparing the investment managers' assessment of the fair values of the Company's Company's investment portfolio balance against the fair values of the Company's Company's investment portfolio balance obtained from an independent source.

There were no Level 3 assets held by the Company as of December 31, 2022 December 31, 2023.

Level 3 liabilities consisted of stock price appreciation milestones associated with the Amended MSK MSKCC License as described in detail in Note 2. To determine the estimated fair value of the stock price appreciation milestones, the Company uses a Monte Carlo simulation methodology which models future Company common stock prices based on several key variables. The assumptions used to calculate the fair value of the stock price appreciation milestones are subject to a significant amount of judgment including the

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expected volatility of the Company's common stock and estimated term, which is based in part on the last valid patent claim date. Fair value measurements are highly sensitive to changes in these inputs and significant changes could result in a significantly higher or lower fair value and resulting expense or gain. Further, as the stock price appreciation milestones are first contingent upon the achievement of a specified clinical milestone, the Company also estimates the fair value of the stock price appreciation milestones based on the probability of achieving the clinical milestone. This assessment is based on several factors including the successful achievement of technological, manufacturing, and regulatory requirements.

A small change in the assumptions and other inputs, such as the price of the Company's common stock, may have a relatively large change in the estimated fair value of the stock price appreciation milestones and associated liability and expense. For example, keeping all other variables constant, a hypothetical 10% increase in the stock price at December 31, 2022 from $10.09 to $11.10 per share would have decreased the income recorded during 2022 by $0.4 million related to the stock price appreciation milestones. Keeping all other variables constant, a hypothetical 10% decrease in the stock price at December 31, 2022 from $10.09 to $9.08 per share would have increased the income recorded during 2022 by $0.4 million related to the stock price appreciation milestones.

The following table presents the changes in fair value of the Company's Level 3 stock price appreciation milestones liability (in thousands):

Balance at December 31, 2021	$ 24,168	$ 24,168
Changes in fair value of stock price appreciation milestones liability	(20,307)	(20,307)
Balance at December 31, 2022	$ 3,861	$ 3,861
Changes in fair value of stock price appreciation milestones liability		(2,515)
Balance at December 31, 2023		$ 1,346

None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented.

6. Property and Equipment

Property and equipment consist of the following (in thousands):

	December 31,		December 31,	
	2022	2021	2023	2022
Furniture and fixtures	$ 1,209	$ 1,209	$ 1,309	$ 1,209
Computer and office equipment	2,937	2,168	3,132	2,937
Software	2,122	1,899	2,130	2,122
Leasehold improvements—building	56,782	52,948	59,038	56,782
Scientific equipment	77,354	50,250	78,853	77,354
Total property and equipment, gross	140,404	108,474	144,462	140,404
Less accumulated depreciation and amortization	(30,384)	(16,945)	(47,626)	(30,384)
Total property and equipment, net	$ 110,020	$ 91,529	$ 96,836	$ 110,020

Depreciation expense related to property and equipment was $13.8 million, $5.9 18.3 million and $3.1 13.8 million, for the years ended December 31, 2022, 2021, December 31, 2023 and 2020, 2022, respectively. No material gains or losses on the disposal of property and equipment have been recorded for the years ended December 31, 2022, 2021, and 2020.

7. Accrued Expenses

Accrued Expenses

Current accrued expenses consist of the following (in thousands):

	December 31,	
	2022	2021
Accrued payroll and other employee benefits	$ 17,899	$ 18,358
Accrued clinical trial related costs	16,858	12,344
Accrued other	19,175	11,710
Total current accrued expenses	$ 53,932	$ 42,412

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	December 31,	
	2023	2022
Accrued payroll and other employee benefits	$ 10,563	$ 17,899
Accrued clinical trial related costs	8,833	16,858
Accrued other	8,118	19,175
Total current accrued expenses	$ 27,514	$ 53,932

8. Leases

The Company has lease agreements for office, laboratory and manufacturing spaces that are classified as operating leases on the consolidated balance sheets.These leases have terms varying from one to approximately sixteen years, , with renewal options of up to ten years, as well as early termination options. Extension and termination options are included in the total lease term when the Company is reasonably certain to exercise them. The leases are subject to additional variable charges, including common area maintenance, property taxes, property insurance and other variable costs. Given the variable nature of such costs, they are recognized as expense as incurred. Additionally, some of the Company's leases are subject to certain fixed fees which the Company has determined to be non-lease components. The Company has elected to combine and account for lease and non-lease components as a single lease single-lease component for purposes of determining the total future lease payments.

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In January 2020, the Company entered into a lease agreement for certain office, laboratory and manufacturing space (the Premises), and such lease is accounted for as an operating lease. The Premises are located in San Diego, California and the Company moved its corporate headquarters to the Premises in August 2021. Lease payments commenced in May 2021 (the Rent Commencement Date) and the lease has a lease term of 15 years starting from the Rent Commencement Date. The Company has the option to extend the lease for two successive five-year periods. The Company also has a one-time option to terminate the lease after 10 years from the Rent Commencement Date, subject to payment of a $30.0 million early termination fee. The landlord of the Premises is obligated to contribute an aggregate of up to $29.8 million toward tenant improvements of the Premises. As of December 31, 2022, the Company had utilized the entire tenant improvements allowance. The Company recorded the tenant improvement allowance as part of the Company's leasehold improvements, which is depreciated in accordance with the Company's Property and Equipment policy. In connection with the lease, the Company maintains a letter of credit for the benefit of the landlord in an amount equal to $15.0 million, which amount is subject to reduction over time.

In November 2021, the Company entered into a lease agreement for certain office space in San Diego, California, and such lease is accounted for as an operating lease. Lease payments commenced, subject to certain conditions, in January 2022 (the Rent Commencement Date) and the lease has a lease term of 6 years starting from the Rent Commencement Date. The Company has no option to extend the lease, and no option to early terminate the lease. Upon lease commencement in December 2021, the Company recorded a right-of-use asset of $6.0 million.

As of December 31, 2022 December 31, 2023, future undiscounted minimum contractual payments under the Company's operating leases were $177.7 162.9 million, which will be paid over a remaining weighted-average lease term of 11.5 10.7 years. The weighted-average discount rate for the operating lease liabilities was 8.28 8.34%, which was the Company's Company's incremental borrowing rate at lease commencement, as the discount rates implicit in the leases could not be readily determined.

The components of lease expense for the years ended December 31, 2022, 2021, December 31, 2023 and 2020 2022 were as follows (in thousands):

	Years Ended December 31,		
	2022	2021	2020
Straight-line lease expense	$ 15,010	$ 15,354	$ 12,076
Variable lease expense	2,614	1,660	2,245
Total operating lease expense	$ 17,624	$ 17,014	$ 14,321

No short-term lease expense was recognized in the years ended December 31, 2022 and 2021. Total short-term lease expense associated with short-term leases for the year ended December 31, 2020 was $1.2 million.

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	Years Ended December 31,	
	2023	2022
Straight-line lease expense	$ 13,159	$ 15,010
Variable lease expense	2,250	2,614
Total operating lease expense	$ 15,409	$ 17,624

Future undiscounted minimum payments under the Company's operating leases as of December 31, 2022 December 31, 2023 are as follows (in thousands):

	Operating Lease Payments	Operating Lease Payments
Years Ending December 31,		

2023	$ 14,597	
2024	14,836	$ 14,659
2025	15,087	15,087
2026	15,540	15,540
2027	16,006	16,006
2028		15,057
Thereafter	101,636	86,579
Total undiscounted lease payments	$ 177,702	$ 162,928
Less: imputed interest	(68,364)	(59,392)
Total lease liability	$ 109,338	$ 103,536

In April 2023, the Company entered into an agreement to sublease approximately 18,913 square feet of space, which sublease agreement commenced in April 2023 and expires in December 2028 with no option to extend the sublease term. Under the sublease agreement, rent is subject to scheduled annual increases and the subtenant is responsible for certain operating expenses and taxes throughout the term of the sublease.

Sublease income is recognized in other income. Sublease income for the years ended December 31, 2023 and 2022 was as follows (in thousands):

	Years Ended December 31,	
	2023	2022
Sublease income	$ 729	$ —

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