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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31 , 2023

OR

o 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 001-40693

RALLYBIO CORPORATION

(Exact name of Registrant as specified in its Charter)

Delaware	**85-1083789**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
234 Church Street , Suite 1020 New Haven , CT	**06510**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (203) 859-3820

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, par value $0.0001 per share	RLYB	The NASDAQ Global Select 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 o No x

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

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 x No o

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 x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	o	Accelerated filer	o
Non-accelerated filer	x	Smaller reporting company	x
		Emerging growth company	x

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. o

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

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

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

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES o NO x

The aggregate market value of the registrant's voting common stock held by non-affiliates as of June 30, 2023 was approximately $ 134.4 million, based on the closing price of the

registrant’s common stock as reported by Nasdaq on that date.

The number of shares of Registrant’s Common Stock outstanding as of March 7, 2024 was 37,811,970 .

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant’s Definitive Proxy Statement for its 2024 Annual Meeting of Stockholders scheduled to be held on May 15, 2024, which Definitive Proxy will be filed with the Securities and Exchange Commission not later than 120 days after the registrant’s fiscal year end of December 31, 2023 are incorporated by reference into Part II and Part III of this Annual Report on Form 10-K.

Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. 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 terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements concerning:

- the initiation, timing, progress, results, and cost of our research and development programs, and our current and future preclinical and clinical studies, including statements regarding the timing of initiation and completion of our clinical trials for RLYB212, RLYB116 and RLYB331, our toxicology program for RLYB212, and the natural history study for our fetal and neonatal alloimmune thrombocytopenia prevention program, and related preparatory work, and the period during which the results of the trials will become available;
- the success, cost and timing of our clinical development of our product candidates, including RLYB212, RLYB116 and RLYB331;
- the potential of our product candidates to treat certain target diseases;
- our ability to initiate, recruit and enroll patients in and conduct our clinical trials at the pace that we project;
- our ability to obtain and maintain regulatory designations allowing for priority review of our product candidates, and our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations or warnings in the label of any of our product candidates, if approved;
- our ability to compete with companies currently marketing or engaged in the development of treatments for diseases that our product candidates are designed to target, including paroxysmal nocturnal hemoglobinuria and generalized myasthenia gravis;
- our reliance on third parties to conduct our clinical trials;
- enhancements to the manufacturing process for RLYB116, and the expected timing of completion thereof;
- our reliance on third parties to manufacture drug substance and drug product for use in our clinical trials;
- the size and growth potential of the markets for RLYB212, RLYB116, RLYB114, RLYB331 and any of our current product candidates or other product candidates we may identify and pursue, and our ability to serve those markets;
- our ability to enter into collaborations, partnerships and other transactions with third parties;
- our ability to identify and advance through clinical development any additional product candidates;
- the commercialization of our current product candidates and any other product candidates we may identify and pursue, if approved, including our ability to successfully build commercial infrastructure or enter into collaborations with third parties to market our current product candidates and any other product candidates we may identify and pursue;
- our ability to retain and recruit key personnel;
- our ability to obtain and maintain adequate intellectual property rights;

- our expectations regarding government and third-party payor coverage and reimbursement;
- our estimates of our expenses, ongoing losses, capital requirements and our needs for or ability to obtain additional financing;
- our expected uses of the net proceeds from our initial public offering and any subsequent offerings;
- the potential benefits of strategic collaboration agreements and arrangements, including our agreements with Exscientia Limited and AbCellera Biologics Inc. and our research collaboration with EyePoint Pharmaceuticals, Inc., and the expected timing of updates related thereto, our ability to enter into strategic collaborations or arrangements, including potential business development opportunities and potential licensing partnerships, and our ability to attract collaborators with development, regulatory and commercialization expertise;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012;
- our financial performance;
- developments and projections relating to our competitors or our industry; and
- other risks and uncertainties, including those listed under the section titled “Risk Factors.”

The forward-looking statements in this Annual Report on Form 10-K are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of known and unknown risks, uncertainties and assumptions, including those described under the sections in this Annual Report on Form 10-K entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Annual Report on Form 10-K. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as guarantees of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual future results, levels of activity, performance and events and circumstances could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risks and uncertainties may emerge from time to time, and it is not possible for management to predict all risks and uncertainties. Except as required by applicable law, we are not obligated to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Trademarks

We use Rallybio as a trademark in the United States ("U.S.") and/or in other countries. This Annual Report on Form 10-K contains references to our trademark and to those belonging to other entities, including Affibody®. Solely for convenience, trademarks and trade names referred to in this Annual Report on Form 10-K, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

Risk Factor Summary

Our business is subject to a number of risks that are discussed more fully in the “Risk Factors” section of this Annual Report on Form 10-K. These risks include the following:

- We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the foreseeable future. We have not commercialized any products and have never generated

revenue from the commercialization of any product. We are not currently profitable, and we may never achieve or sustain profitability;

- We will require significant additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of RLYB212, RLYB116 or any additional product candidates we may develop;
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates;
- We are heavily dependent on the success of RLYB212 and RLYB116, which are in early-stage clinical development. If we are not able to develop, obtain regulatory approval for, or successfully commercialize our product candidates, or if we experience significant delays in doing so, our business will be materially harmed;
- We may not be successful in our efforts to identify additional product candidates. Due to our limited resources and access to capital, we must prioritize development of certain product candidates, the choice of which may prove to be wrong and adversely affect our business;
- Preclinical studies and clinical trials are expensive, time consuming and difficult to design and implement, and involve uncertain outcomes. Any product candidates that we advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates;
- Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including our focus on rare diseases;
- Results of preclinical studies, clinical trials or analyses that we may announce or publish from time to time, may not be indicative of results obtained in later trials, and any interim results we may publish could be different than final results;
- Any product candidates that we develop or the administration thereof, may cause serious adverse events or undesirable side effects, which may halt their clinical development, delay or prevent marketing approval, or, if approved, require them to be taken off the market, include safety warnings, or otherwise limit their sales;
- The regulatory approval processes of the U.S. Food and Drug Administration (the "FDA"), the European Medicines Agency (the "EMA"), and comparable foreign regulatory authorities, including the Medicines and Healthcare products Regulatory Agency in the United Kingdom (the “MHRA”), are lengthy, time-consuming, and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for RLYB212, RLYB116 or any of our other product candidates, our business will be substantially harmed;
- Our product candidates target rare diseases and conditions, and the market opportunities for RLYB212, RLYB116 or any of our other product candidates, if approved, may be smaller than we anticipate. As a result, our commercial opportunity may be limited and because the target populations of our product candidates are for rare diseases, we must be able to successfully identify patients and capture a significant market share to achieve profitability and growth;

- The FDA, EMA or other comparable foreign regulatory authorities, including the MHRA, could require the clearance or approval of an in vitro diagnostic or companion diagnostic device as a condition of approval for any product candidate that requires or would commercially benefit from such tests, including RLYB212. Failure to successfully validate, develop and obtain regulatory clearance or approval for companion diagnostics on a timely basis or at all could harm our drug development strategy and we may not realize the commercial potential of any such product candidate;

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

- We intend to continue to pursue business development transactions focused on the in-license of additional product candidates or the out-license of rights to product candidates in our pipeline and collaborate with third parties for the development and commercialization of our product candidates. We may not succeed in identifying and acquiring businesses or assets, in-licensing intellectual property rights or establishing and maintaining collaborations, which may significantly limit our ability to successfully develop and commercialize our other product candidates, if at all, and these transactions could disrupt our business, cause dilution to our stockholders or reduce our financial resources; and

- If we are unable to obtain, maintain and enforce patent protection for our technology and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected.

The foregoing is only a summary of some of our risks. For a more detailed discussion of these and other risks you should consider before making an investment in our common stock, see “Risk Factors.”

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PART I

Item 1. Business.

Overview

We are a clinical-stage biotechnology company comprised of experienced biopharma industry leaders with extensive research, development, and rare disease expertise with a mission to develop and commercialize life-transforming therapies for patients with severe and rare diseases. Since our launch in January 2018, we have built a broad pipeline of promising product candidates aimed at addressing diseases with unmet medical need in the areas of maternal fetal health, complement dysregulation, hematology, and metabolic disorders. Our two most advanced programs are in clinical development: RLYB212, an anti-HPA-1a antibody for the prevention of fetal and neonatal alloimmune thrombocytopenia (“FNAIT”) and RLYB116, an inhibitor of complement component 5 (“C5”), with the potential to treat several diseases of complement dysregulation. Both programs have completed Phase 1 clinical trials, and we currently plan to initiate a Phase 2 clinical trial of RLYB212 in the second half of 2024.

Our Approach

At Rallybio Corporation (“Rallybio” or the "Company"), we do not accept that millions of patients suffering from devastating rare diseases should have to live without transformative treatments. There are an estimated 25 to 30 million people affected by as many as 7,000 rare diseases in the United States alone, with a significantly greater number affected globally. Our goal is to transform the lives of these individuals through the development of therapeutics that provide meaningful clinical benefits.

We believe the long-term success of the Company is built on our key strengths:

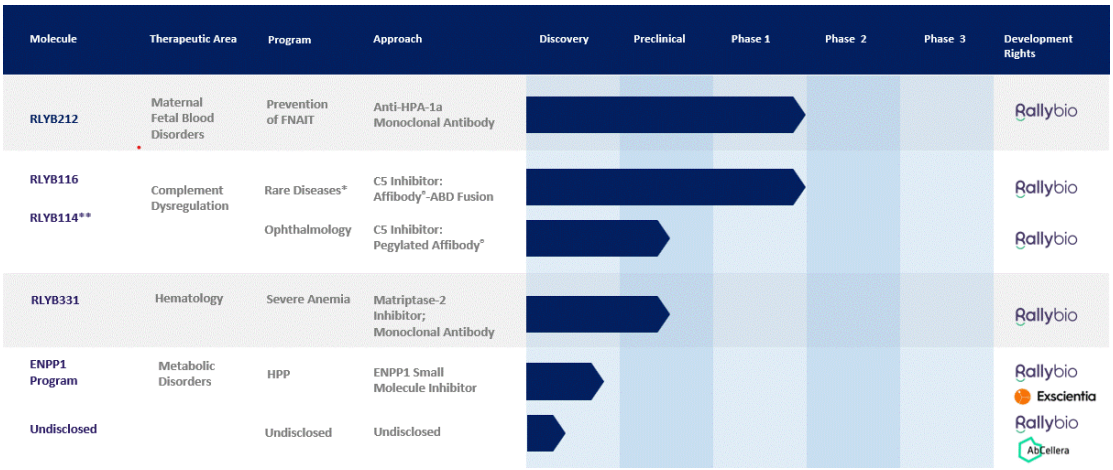
- **Our team’s proven execution capability to drive product candidates through clinical development to marketing approvals.** We have assembled a team with a proven history of successfully advancing product candidates from discovery to clinical development and through marketing approval. Members of our team have played critical roles in the approval of more than 30 drugs, including seven approvals for rare disease therapeutics since 2013, and secured approvals from regulatory authorities in the Americas, Europe, Australia, and Asia. In doing so, our employees previously developed and implemented novel clinical trial designs and successfully conducted clinical trials in previously underserved patient populations, including those impacted by diseases lacking approved therapies. We believe this collective prior experience positions us to efficiently and expertly execute at each step in the research and development process and enhances the value we can bring to our product candidates and patients.
- **Our extensive knowledge of rare diseases and our scientific expertise positions us to identify therapies with the potential for transformative impact.** Although we intend to focus our near-term efforts on maximizing the value of our current portfolio, we may in the future opportunistically seek to acquire and develop product candidates that possess a clear mechanism of action and that aim to address diseases with a well-understood pathophysiology for which there is a significant unmet medical need. We believe that a product candidate’s mechanism of action should target the causal biology of the disease to provide the highest probability of dramatically improving the lives of patients. We also believe that our team’s extensive experience in rare diseases and overall deep scientific expertise position us to identify opportunities where these links can be made. In addition, our ability to source these product candidates is facilitated by our extensive network of relationships with leaders in industry and in academic centers worldwide.

Our Team

Our Chief Executive Officer, Stephen Uden, M.D., and Executive Chairman, Martin W. Mackay, Ph.D., previously worked together in different organizations to successfully build, develop, and launch transformative therapies for patients with rare diseases. In addition, several members of our team were integral in the successful development and/or approval of therapies such as Strensiq (asfotase alfa) for patients with perinatal-, infantile-, and juvenile-onset hypophosphatasia ("HPP"), Kanuma (sebelipase alfa) for patients with lysosomal acid lipase deficiency, Nulibry (fosdenopterin) for patients with molybdenum cofactor deficiency, Soliris (eculizumab) for patients with refractory generalized myasthenia gravis ("gMG"), Soliris for patients with relapsing neuromyelitis optica spectrum disorder ("NMOSD"), Ultomiris (ravulizumab-cwvz) for patients with paroxysmal nocturnal hemoglobinuria ("PNH") and Ultomiris for patients with atypical hemolytic uremic syndrome ("aHUS").

Our Pipeline

Our pipeline is illustrated in the chart below:



FNAIT: Fetal and neonatal alloimmune thrombocytopenia; HPA-1a: Human platelet antigen-1a; C5: Complement component 5; ABD: Albumin-binding domain; HPP: Hypophosphatasia; ENPP1: Ectonucleotide pyrophosphatase/phosphodiesterase 1

*Disease areas under consideration: hematology, including disorders such as PNH and antiphospholipid syndrome; and neurology, including disorders such as gMG

** Rallybio and EyePoint Pharmaceuticals are conducting an evaluation to assess the viability of using EyePoint's delivery technology with Rallybio's complement inhibitor; following the evaluation, the parties will determine whether to advance the collaboration, in which case EyePoint would assume development rights

Prevention of FNAIT

We are developing RLYB212 for the prevention of FNAIT. FNAIT is a potentially life-threatening rare disease that can cause uncontrolled bleeding in fetuses and newborns that can arise during pregnancy due to an immune incompatibility between an expectant mother and her fetus in a specific platelet antigen called human platelet antigen 1 ("HPA-1"). This incompatibility can cause an expectant mother to develop antibodies that attack the platelets of her fetus. The destruction of platelets in the fetus can result in severely low platelet counts, or thrombocytopenia, potentially leading to devastating consequences including miscarriage, stillbirth, death of the newborn, or severe lifelong neurological disability in those babies who survive. There is currently no approved therapy for the prevention or treatment of FNAIT.

We estimate that there are over 22,000 pregnancies at high risk of developing FNAIT each year in the United States, Canada, the United Kingdom (the "UK"), other major European countries and Australia. Since, there are no approved therapies to prevent FNAIT, expectant mothers are not currently screened for the risk of FNAIT. As a result, the vast majority of pregnancies at risk for FNAIT go unidentified and untreated. In those pregnancies that are identified as at-risk, typically due to the delivery of a prior FNAIT affected child, expectant mothers may be treated with weekly intravenously-administered high doses of immunoglobulin G ("IVIG"), along with the oral steroid immunosuppressant prednisone. However, IVIG administration does not prevent the immune response, called alloimmunization, and is costly, time-intensive, difficult to tolerate and associated with significant treatment-related complications. Based on the data generated to date and the clinical precedent for effective prevention of maternal alloimmunization by anti-RhD prophylaxis, which has resulted in the virtual elimination of Rhesus disease, we believe that targeting HPA-1a with an anti-HPA-1a antibody has the potential to drive rapid elimination of HPA-1a positive platelets from the circulation of expectant mothers, prevent alloimmunization and thereby prevent the occurrence of FNAIT.

We have completed two RLYB212 clinical trials: a Phase 1 first-in-human clinical trial and a Phase 1b proof of concept clinical trial. The Phase 1 first-in-human clinical trial was a single-blind, placebo-controlled study that investigated the safety and pharmacokinetics (“PK”) of subcutaneous (“SC”) administration of RLYB212 in HPA-1a negative healthy participants. The clinical trial included a single dose cohort and a multiple dose cohort. In the multiple dose cohort, subjects received SC RLYB212 or placebo every two weeks for 12 weeks. We reported preliminary results from the multi-dose cohort in the fourth quarter of 2023. The data and our clinical pharmacology modeling predictions support a once monthly dosing regimen for the planned Phase 2 clinical trial. RLYB212 was observed to be generally well-tolerated with no reports of injection site reactions or serious adverse events.

The Phase 1b single-blind, placebo-controlled proof-of-concept clinical trial was designed to establish the ability of SC RLYB212 to rapidly eliminate HPA-1a positive platelets transfused to HPA-1a negative healthy subjects. The study included 11 males aged 18 to 65 years, randomized to RLYB212 0.09mg (n=4), RLYB212 0.29mg (n=5), or placebo (n=2). We reported the results from this trial at the 31st Congress of the International Society on Thrombosis and Haemostasis ("ISTH") in the second quarter of 2023. The results showed that SC RLYB212 administration produced a dose-dependent, rapid, and complete elimination of transfused HPA-1a positive platelets in HPA-1a negative subjects, with both doses meeting the prespecified proof-of-concept criteria of ≥90% reduction in mean platelet elimination half-life. Mean platelet elimination half-life was 5.8 hours (0.09mg dose) and 1.5 hours (0.29mg dose) for RLYB212 compared to 71.7 hours for placebo. Consistent with the Phase 1 first-in-human trial, RLYB212 was observed to be well-tolerated with no reports of serious or severe adverse events.

Additionally, we are conducting a FNAIT Natural History Alloimmunization Study ("FNAIT natural history study"). This prospective, non-interventional, multinational natural history study is designed to screen up to 30,000 expectant mothers presenting at gestational week 10 to 14 prenatal visit to determine the frequency of women at higher FNAIT risk among expectant mothers of different racial and ethnic characteristics, as well as the frequency of HPA-1a alloimmunization and pregnancy outcomes among these women. Subject to future discussions with regulatory authorities, we expect that data from this study will contribute to a control dataset for a future single-arm Phase 3 registrational clinical trial for RLYB212. An additional objective of the FNAIT natural history study is to operationalize de novo the laboratory screening test paradigm for FNAIT risk and generate FNAIT laboratory test performance data that we plan to use for future regulatory discussions. As of March 1, 2024, approximately 9,400 women have been screened as part of the study.

Treatment of Disorders Due to Complement Dysregulation

The complement system plays a central role in innate immunity, as well as, shaping adaptive immune response. Dysregulation of the complement pathway has been implicated in the pathogenesis of a growing number of diseases, making it an attractive target for therapeutic intervention. Antibody inhibitors of C5 have been successfully developed to treat diseases caused by complement pathway dysregulation, including PNH, aHUS, refractory gMG and relapsing NMOSD. Despite the approval of antibody-based C5 inhibitors for patients with these diseases, we believe there remains a significant need in the market for safe, effective, patient-friendly, and accessible therapies.

Our team has a track record of success in designing, developing, and securing marketing approval for C5 complement inhibitors, including Soliris and Ultomiris, for patients around the world with severe and rare complement-mediated diseases. Our most advanced product candidate in this therapeutic area is RLYB116, an inhibitor of C5, which is a central component of the terminal complement pathway. RLYB116 is an Affibody molecule attached to an albumin binding domain that has the potential to drive the rapid, complete, and sustained inhibition of C5 with a SC injection. We have completed a Phase 1 clinical trial in healthy participants that included the study of RLYB116 as both a single ascending dose (“SAD”) and a multiple ascending dose (“MAD”).

The SAD portion of the RLYB116 Phase 1 trial included five cohorts with doses ranging from 2mg up to 300mg. Data from the SAD portion of the RLYB116 trial showed that all study participants that were administered a single 1 mL SC injection of 100 mg of RLYB116 (n=6) demonstrated a reduction in free C5 greater than 99% within 24 hours of dosing. Subcutaneously administered RLYB116 in the SAD portion of the trial was observed to be generally well-tolerated at the 100 mg dose, with mild adverse events and no drug-related serious adverse events reported. The terminal elimination half-life of RLYB116 was greater than 300 hours. The MAD portion of the RLYB116 Phase 1 trial included an adaptive single-blind design with a four-week treatment duration to evaluate the safety, tolerability, PK, and pharmacodynamics ("PD") of RLYB116 with multiple dose SC administration. The MAD portion of the trial included four cohorts: Cohort 1 (weekly dosing of 100 mg), Cohort 2 (3 doses of 100 mg the first week followed by weekly dosing), Cohort 3 (150 mg weekly dosing reduced to 125 mg weekly dosing) and Cohort 4 (75 mg twice the first week followed by 100 mg twice per week) with post-treatment for 10 weeks. In December 2023, we reported data from the MAD portion of the trial that demonstrated a 100 mg low volume (1 mL) once-weekly dose of subcutaneously administered RLYB116 achieved sustained mean reductions in free C5 of greater than 93%, including at Day 29 with measurement prior to the last dose. The reduction from pre-treatment free C5 at 24 hours after the first dose of 100 mg was greater than 99%. In the MAD portion of the Phase 1 trial, RLYB116 demonstrated low inter-subject variability and consistent increases in exposure relative to dose with a mean estimated elimination half-life for RLYB116 of

>300 hours. RLYB116 administered in the MAD trial as a 100 mg once-weekly dose was also observed to be generally well tolerated.

Based on data from the MAD portion of the Phase 1 trial and additional work we have conducted with RLYB116, we believe that RLYB116 has the potential to be an effective treatment for patients with certain complement-mediated diseases, including gMG. We have prioritized enhancements to the manufacturing process that are intended to improve tolerability at higher doses with a low injection volume and infrequent SC administration, thereby opening up the opportunity to treat a wider range of complement-mediated diseases in addition to gMG, including PNH and antiphospholipid syndrome. We expect the manufacturing work to be completed in the second half of 2024.

Our second C5 inhibitor, RLYB114, is a pegylated C5-targeted Affibody molecule with PK properties designed for the treatment of complement-mediated ophthalmic diseases. In February 2023 we entered into a collaboration with EyePoint Pharmaceuticals, Inc. (“EyePoint”) and are using EyePoint’s proprietary technology for sustained intraocular drug delivery, with the initial focus on geographic atrophy, an advanced form of age-related macular degeneration that leads to irreversible vision loss. Rallybio and EyePoint expect to provide an update on this collaboration in the first half of 2024.

Hematological Disorders

In May 2022, we obtained worldwide exclusive rights to RLYB331, a preclinical, monoclonal antibody that is designed to inhibit Matriptase-2 ("MTP-2"). The inhibition of MTP-2 significantly increases levels of hepcidin, decreases iron load and treats ineffective erythropoiesis. We believe RLYB331 has the potential to address a significant unmet need for patients with severe anemia with ineffective red blood cell production or erythropoiesis and iron overload, such as polycythemia vera, beta thalassemia and a subset of myelodysplastic syndromes ("MDS"), amongst others. Currently these patients are underserved by the existing standard of care. We are continuing with preclinical activities to support the transition of RLYB331 into clinical development and expect to report data from this program in the first half of 2024.

Artificial Intelligence Drug Discovery Collaboration

In July 2019, we formed a joint venture with Exscientia Limited ("Exscientia"), an Oxford, UK-based artificial intelligence ("AI") and machine learning drug discovery company with a proprietary chemical design platform to discover novel small molecule drug candidates. Our joint venture is focused on the discovery and development of small molecule therapeutics for the treatment of patients with rare metabolic diseases.

The joint venture is currently developing a small molecule targeting an Ectonucleotide Pyrophosphatase/ Phosphodiesterase 1 ("ENPP1") inhibitor for the treatment of HPP. HPP is a rare, genetic disease characterized by mutations in the ALPL gene. The ALPL gene provides instructions for making an enzyme called tissue-nonspecific alkaline phosphatase, which plays an important role in the growth and development of bones and teeth. The incidence of HPP has been reported to be 1 in 100,000 to 1 in 300,000 (United States and Canada) for severe disease and 1 in 6,370 (European Union) for less severe forms. These mutations lead to diminished activity of the alkaline phosphatase enzyme and the accumulation of inorganic pyrophosphate (“PPi”), which inhibits bone mineralization causing multiple skeletal pathologies. We believe that a small molecule inhibitor of ENPP1 has the potential to bring meaningful benefit to HPP patients by reducing excess levels of pyrophosphate, thereby removing an inhibitor of calcium mineralization and bone formation.

We and Exscientia continue to work toward the selection of a small molecule development candidate to advance into the clinic targeting ENPP1 for the treatment of patients with HPP. Proof of mechanism studies are in progress with a leading global HPP expert. We plan to provide an update on the progress of the program in the second half of 2024.

AbCellera Collaboration

In December 2022, we entered into a strategic alliance to discover, develop, and commercialize novel antibody-based therapeutics for rare diseases. This multi-year, multi-target collaboration will combine AbCellera Biologic's ("AbCellera") antibody discovery engine with Rallybio’s clinical and commercial expertise in rare diseases to identify optimal clinical candidates with a goal of delivering therapies to patients.

AbCellera and Rallybio will co-develop up to five rare disease therapeutic targets, which will be chosen together by both companies. The collaboration will allow Rallybio to add product candidates to our existing pipeline with the option for AbCellera to conduct process development and clinical manufacturing activities. The first program is focused on addressing the significant unmet therapeutic needs of patients with rare metabolic diseases.

Our Strategy

Our mission is aligned with our expertise: to identify and accelerate the development of life-transforming therapies for patients with severe and rare disorders. To achieve this mission, our strategy includes the following key components:

- **Establish a leading rare disease company with a team that delivers transformative medicines to patients.** We believe our team's expertise and knowledge are fundamental to our long-term success. Our research and development team is led by experienced drug development executives who were integral in the approvals of more than 30 drugs from leading companies, including Alexion Pharmaceuticals, Inc, Astellas Pharma Inc., Pfizer Inc. and Wyeth, LLC. We plan to create value by continuing to leverage our team's expertise and focus on further development of our current product candidates either alone or through partnerships and collaborations to significantly improve the lives of patients.
- **Advance RLYB212 for the prevention of FNAIT.** There is currently no approved therapy for the prevention of FNAIT. Women at higher risk of FNAIT may experience potentially devastating outcomes and we believe there is a significant unmet need for patients. We believe the clinical data generated to date support continued investment and development of RLYB212 and provide us with an opportunity to deliver a substantially impactful therapeutic in maternal fetal health for expectant mothers with FNAIT. Furthermore, we estimate that the market opportunity exceeds $1 billion. We plan to initiate a Phase 2 study in expectant mothers at higher risk of FNAIT in the second half of 2024.
- **Advance RLYB116 for the treatment of diseases of complement dysregulation through partnering or other forms of non-dilutive financing.** In the fourth quarter of 2023, we announced preliminary data from a MAD Phase 1 trial of RLYB116. Based on the data from this trial, we believe that RLYB116 has the potential to be an effective treatment for patients with certain complement-mediated diseases, including gMG. We are currently implementing additional manufacturing process improvements that we believe will enable RLYB116 to treat a broader range of complement-mediated diseases. Given our desire to conserve capital, we will seek to move this program forward with a partner or non-dilutive financing.
- **Leverage the progress made to date and maximize the value from our preclinical candidates, including the programs in our collaborations with Exscientia and AbCellera.** We believe that our preclinical pipeline programs have significant potential to generate value by meeting the unmet needs of patients and we intend to continue to move these forward in a capital-efficient manner. For example, we are currently conducting preclinical work for RLYB331 and expect to report the results of this work in the first half of 2024 prior to initiating any further development work. In addition, we are continuing to support our collaborations with Exscientia and AbCellera with a goal of generating additional data from these programs that can inform the most appropriate next steps in development.
- **Create value from our pipeline through targeted business development activities.** We believe we have assembled a valuable portfolio of product candidates targeting several rare diseases and will seek to unlock that value by leveraging our current and potential future partnerships and collaborations for one or more of these programs. We believe this will enable us to advance these programs while focusing our development efforts and related spend on RLYB212. We may also periodically evaluate the potential in-license or acquisition of new programs subject to market conditions and our cash runway.

Our Product Candidates

RLYB212 for the prevention of FNAIT

RLYB212 is a subcutaneously administered monoclonal anti-HPA-1a antibody for the prevention of FNAIT, a maternal fetal blood disorder that can cause potentially devastating outcomes in the fetus or neonate including miscarriage, neonatal death, and severe life-long neurological disability in the babies that survive. We have completed two Phase 1 clinical trials for RLYB212 and we intend to initiate the Phase 2 clinical trial for RLYB212 in the second half of 2024. Based on the preclinical and clinical data to date and our understanding of FNAIT, we believe RLYB212 has the potential to prevent maternal alloimmunization and thereby the occurrence of FNAIT.

We are also currently conducting an FNAIT natural history study. This prospective, non-interventional, multinational study is designed to determine the frequency of women at higher FNAIT risk among expectant mothers of different racial and ethnic characteristics, as well as the frequency of HPA-1a alloimmunization and pregnancy outcomes among these women. We expect that data from this study will contribute historical control data to support a planned single-arm Phase 3 registrational clinical trial of RLYB212. An additional objective of the FNAIT natural history study is to operationalize de novo the laboratory screening test paradigm for FNAIT risk and generate FNAIT laboratory test performance data for future regulatory discussions.

Maternal fetal blood disorders

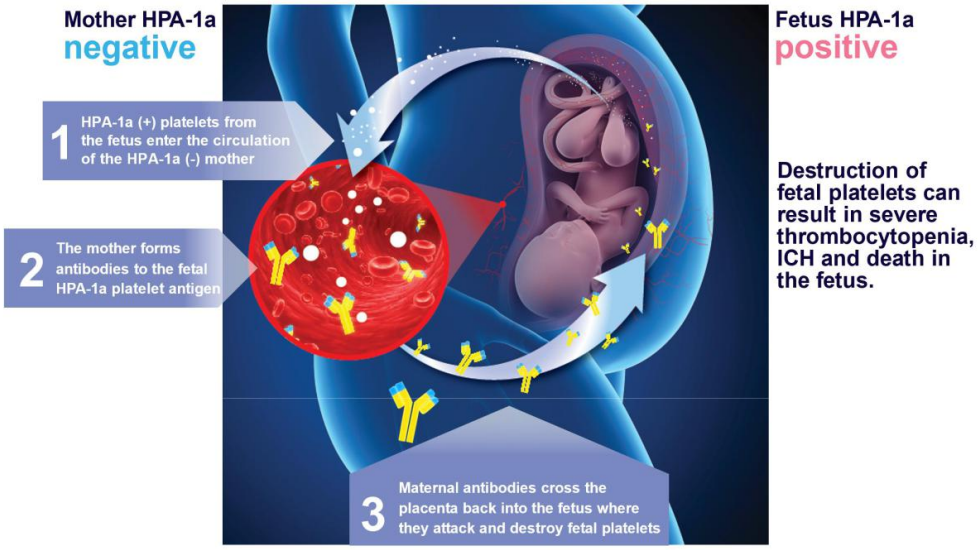
FNAIT is one of several devastating disorders that is caused by an immune incompatibility of a mother and fetus during pregnancy. One of the best-characterized prenatal immune incompatibility disorders is Rh disease. This condition arises when the mother is RhD negative and her fetus is RhD positive. RhD incompatibility may lead to destruction of red blood cells in the fetus and can result in severe outcomes including miscarriage or loss of a newborn. Rh disease is treated by giving at-risk expectant mothers low doses of antibodies to RhD. These antibodies remove fetal red blood cells that have crossed into the mother's circulation, thereby preventing her from developing an immune response that could destroy the red blood cells in the fetus. Since the approval of the first Rho (D) Immune Globulin in 1968, known as RhoGAM, expectant mothers in many countries, including in North America and Europe, are routinely screened for their RhD status, and Rh disease is largely prevented in at-risk expectant mothers. We are pursuing a similar approach to prevent FNAIT.

FNAIT disease background

Like Rh disease, FNAIT is a disorder that occurs during pregnancy when an expectant mother's immune system attacks a specific antigen on the blood cells of her fetus, leading to their destruction. This results in an increased risk of bleeding in the fetus and newborn. In the majority of cases, the effects of FNAIT are mild; however, up to 20% of FNAIT cases experience intracranial hemorrhage ("ICH"), which can lead to devastating outcomes such as miscarriage, stillbirth, loss of the newborn and severe lifelong neurological disabilities in those babies that survive.

FNAIT is caused by a mismatch in the type of HPA-1 that is expressed by the expectant mother and the fetus. There are two predominant forms of HPA-1, known as HPA-1a and HPA-1b, which are expressed on the surface of platelets. These two alleles differ by a single amino acid. Individuals who are homozygous for HPA-1b, meaning that they have two copies of the HPA-1b allele and no copies of the HPA-1a allele, are also known as HPA-1a negative. Upon exposure to HPA-1a, these individuals can develop antibodies to that antigen in a process known as alloimmunization. In expectant mothers, alloimmunization can occur upon mixing of fetal blood with maternal blood. When alloimmunization occurs in an expectant mother, the anti-HPA-1a antibodies that develop in the mother can cross the placenta and destroy platelets in the fetus.

Pathophysiology of FNAIT



There are no approved therapies to treat or prevent FNAIT and expectant mothers are not currently screened for FNAIT risk. Today, expectant mothers at risk of FNAIT are typically only identified following the delivery of an FNAIT affected child. These mothers may be treated during subsequent pregnancies with weekly administration of IVIG, along with the oral steroid immunosuppressant prednisone. While IVIG administration can potentially mitigate the detrimental effects of anti-HPA-1a antibodies, it does not prevent alloimmunization, is costly, time-intensive, difficult to tolerate and associated with significant treatment-related complications.

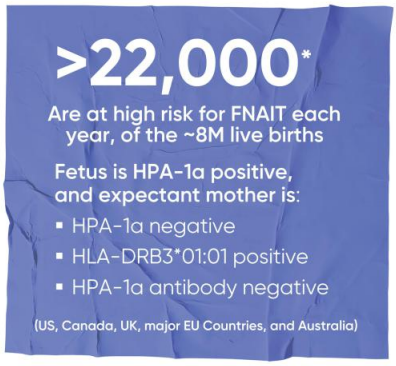
Babies with FNAIT are typically diagnosed at the time of delivery by the presence of low platelet counts identified during routine analysis, the presence of petechiae on the skin or due to the manifestations of severe complications such as ICH or gastrointestinal bleeding. Upon diagnosis, babies with FNAIT may receive platelet transfusions and may be admitted to the neonatal intensive care unit. In severe cases, babies may suffer life-long neurological disability or may not survive.

Based on published data, we believe that there are at least 22,000 pregnancies annually that are at high risk of FNAIT in the United States, Canada, the UK, other major European countries, and Australia. These pregnancies represent expectant mothers who are HPA-1a negative, who are at high risk of alloimmunization and who are carrying an HPA-1a positive fetus.

Studies show that approximately 2% of the Caucasian population is HPA-1a negative. Based on this frequency and live birth rates of Caucasian women from 2018, we estimate that there are approximately 110,000 HPA-1a negative expectant mothers in the aforementioned countries each year. From this population of expectant mothers, a subset is at higher risk of FNAIT due to the presence of a specific HLA allele, known as DRB3*01:01. Genetic studies have found that expectant mothers who have this specific HLA allele are approximately 25 times more likely to develop antibodies to HPA-1a than those without this allele. This higher-risk population represents approximately 27% of HPA-1a negative expectant mothers, or approximately 30,000 individuals.

From this higher-risk population, an estimated 89% of women would not already have antibodies to HPA-1a and, of these, an estimated 86% would be expected to be carrying an HPA-1a positive fetus. We believe this portion of the higher-risk population could potentially benefit from administration of a monoclonal anti-HPA-1a antibody such as RLYB212.

Pregnancies At High Risk of FNAIT Each Year



***Source: NCHS National Vital Statistics Report Volume 68, Number 13, November 30, 2019, Births: Final Data for 2018; World Bank Population Data (2018); Kjeldsen-Kragh, et al Blood 2007; Hardy-Weinberg estimate; Kjeldsen-Kragh et al Blood 110, 833-839 (2007)**

Given the well-established prevalence of HPA-1a negativity in the Caucasian population, our current estimates of the FNAIT at-risk population are derived from the estimated proportion of Caucasian births from approximately eight million live births per year in the above-mentioned countries. We are committed, however, to ensuring that all expectant mothers of any race or ethnicity who are at high risk of FNAIT are identified and eligible for treatment. To this end, we are conducting a FNAIT natural history study, in part to obtain more precise prevalence estimates of the FNAIT at-risk population in racial and ethnic groups that may have been underrepresented in previously published studies. We believe that data from this study will more precisely inform the size of the FNAIT at-risk population.

We believe that screening for FNAIT risk can be performed routinely and cost effectively as part of standard prenatal testing provided to expectant mothers during pregnancy. Testing for maternal HPA-1 type and presence of the HLA-DRB3*01:01 allele could occur during the first trimester, and at the same time as other routine blood work and risk screening. We don't expect that an additional blood draw would be required. Importantly, U.S. and EU physicians have advised that our approach and timing for FNAIT screening would fit well within the established first trimester prenatal testing paradigm and could be performed at the same time as routine blood typing and Rh testing. Based on our global market research with maternal-fetal medicine specialists, obstetricians-gynecologists and payers, we believe there is high awareness of the catastrophic impact of FNAIT, and a strong desire to both screen and provide preventive therapy to at-risk expectant mothers if there were an approved product to prevent FNAIT and affordable screening tests.

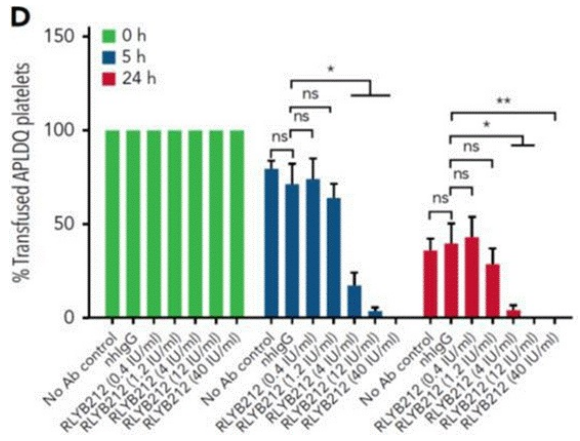
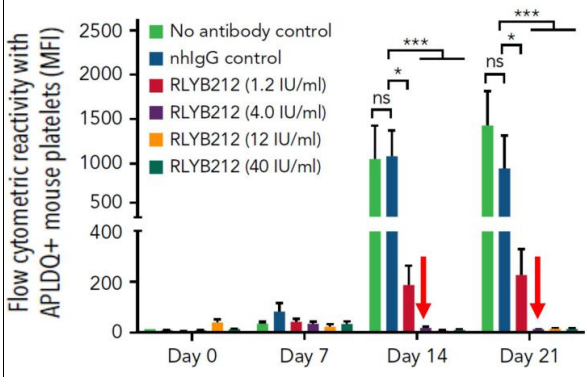
We believe screening and preventive treatment can have a significant impact on this potentially devastating disease. For example, screening and treatment in Rh disease have been highly effective in reducing the number of affected births. In developed countries with access to prenatal testing and treatment, the prevalence of Rh disease is 2.5 per 100,000 compared to 276 per 100,000 worldwide. We believe that applying a similar approach to the prevention of FNAIT could lead to a significant reduction in the number of babies at risk for FNAIT. In our FNAIT natural history study, we are using screening tests for maternal HPA-1 type, maternal HLA-DRB3*D1:01 status, maternal HPA-1a antibodies and fetal HPA-1 genotype.

Our solution: RLYB212

RLYB212 preclinical data

A mouse model of FNAIT has been created in which the amino acids comprising the HPA-1a antigen are reconstituted in the mouse gene. These transgenic mice (referred to as APLDQ mice based on the amino acid changes) recapitulate multiple aspects of FNAIT. Administration of anti-HPA-1a antibodies to APLDQ mice leads to destruction of APLDQ platelets and severe thrombocytopenia. Injection of platelets from APLDQ mice into wild-type mice can induce an HPA-1a specific immune response. Finally, wild-type female mice pre-immunized with APLDQ platelets, when bred with APLDQ male mice, give birth to severely thrombocytopenic pups, many of which exhibit an accompanying bleeding phenotype. Treatment of these pregnant female mice with IVIG resulted in lowering the level of anti-APLDQ antibodies in the fetus and a reduction in thrombocytopenia.

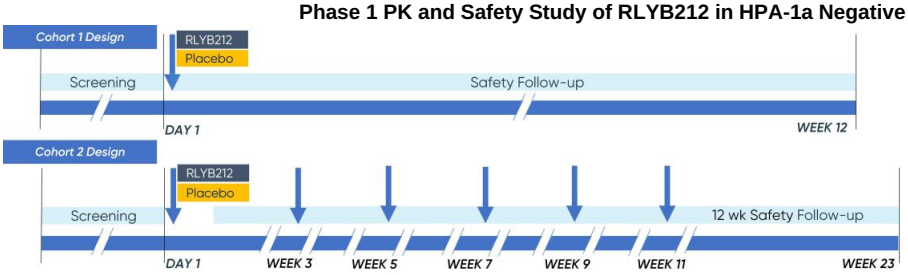
In a prophylactic treatment model, a single large bolus intravenous injection of 1 x 108 APLDQ platelets (equivalent to about one-sixth of the total blood volume in the host) was administered to wild-type mice. At a dose of 0.4 µg (yielding a peak concentration of approximately 0.2 µg/ml), RLYB212 was able to drive rapid and complete elimination of APLDQ platelets, as shown in the first graph below, and prevent a host antibody response, as shown in the second graph below. Also shown in the graphs below, this dose correlates to a concentration of RLYB212 projected to bind approximately 10% of the HPA-1a antigen present on the transfused APLDQ platelets. Thus, the approximately 10% receptor binding is sufficient to clear platelets and prevent alloimmunization in the mouse model.

RLYB212 Induced Rapid Elimination of APLDQ Platelets	RLYB212 Prevented the Development of Antibodies to APLDQ Platelets
	

RLYB212 Clinical Development

We have completed two RLYB212 clinical trials, a Phase 1 first-in-human trial and a Phase 1b proof-of-concept trial. The Phase 1 first-in-human clinical trial is a single-blind, placebo-controlled study that investigated the safety and PK of SC administration of RLYB212 in HPA-1a negative healthy participants. The clinical trial included a single dose cohort and a multiple dose cohort. In the multiple dose cohort, subjects received SC RLYB212 or placebo every two weeks for 12 weeks. An overview of the study's design is illustrated below.

Phase 1 PK and Safety Study of RLYB212 in HPA-1a Negative Healthy Participants

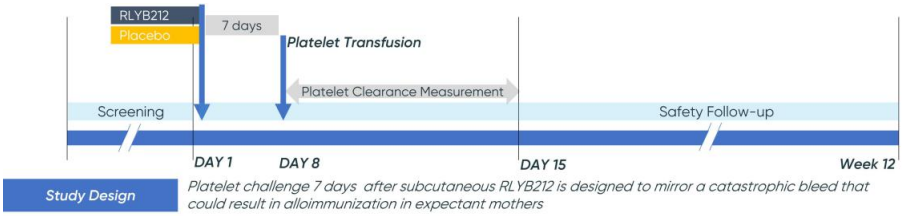


We reported preliminary results from the multi-dose cohort in the fourth quarter of 2023. The data demonstrated that multiple dose PK were consistent both within and between subjects. The data and our clinical pharmacology modeling predictions support a once monthly dosing regimen for the planned Phase 2 study. RLYB212 was observed to be generally well-tolerated with no reports of injection site reactions or serious adverse events.

The Phase 1b single-blind, placebo-controlled proof-of-concept trial was designed to establish the ability of SC RLYB212 to rapidly eliminate HPA-1a positive platelets transfused to HPA-1a negative healthy subjects. The

study included 11 males aged 18 to 65 years, randomized to RLYB212 0.09mg (n=4), RLYB212 0.29mg (n=5), or placebo (n=2). An overview of the study's design is illustrated below.

Phase 1b Trial of RLYB212 in Healthy Male Participants

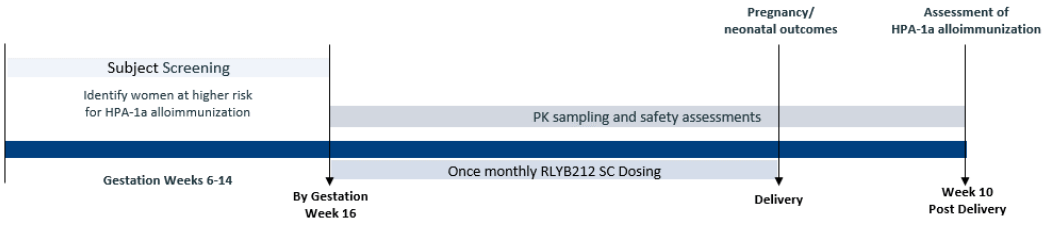


In June 2023, we reported the results from this clinical trial at ISTH. The results showed that SC RLYB212 administration produced a dose-dependent, rapid and complete elimination of transfused HPA-1a positive platelets in HPA-1a negative subjects, with both doses meeting the prespecified proof-of-concept criteria of ≥90% reduction in mean platelet elimination half-life. Mean platelet elimination half-life was 5.8 hours (0.09mg dose) and 1.5 hours (0.29mg dose) for RLYB212 compared to 71.7 hours for placebo. Consistent with the Phase 1 first-in-human trial, RLYB212 was observed to be well-tolerated with no reports of serious or severe adverse events.

Both the U.S. FDA and the EMA have designated RLYB212 as an orphan drug. Orphan drug designations offer certain incentives including tax credits, marketing exclusivity upon any approval, fee waivers, and the ability to interact with both agencies to receive specialized regulatory advice and assistance. We recently engaged with the EMA in such a process in advance of our planned Phase 2 clinical trial. We received feedback from the EMA and are now moving forward with our Clinical Trial Application to support conduct of the Phase 2 study in Europe.

Based on the data generated to date and subject to completion of regulatory discussions, we plan to initiate a Phase 2 trial of RLYB212 in expectant mothers at higher FNAIT risk in the second half of 2024. The primary objective of the Phase 2 clinical trial will be to assess the PK and safety of SC RLYB212 administered antenatally in expectant mothers. Additional objectives will include assessing the safety of RLYB212 in the neonate and neonatal exposure of RLYB212 at time of birth, and assessing pregnancy and neonatal outcomes as well as the occurrence of emergent HPA-1a alloimmunization. We are designing the trial as a single-arm, open-label study and plan to conduct the trial in Europe. The intended study population is women who are at higher risk for HPA-1a alloimmunization and FNAIT (i.e., women who are identified through screening to be HPA-1a negative and HLA-DRB3*0101 positive), who are bearing an HPA-1a positive fetus and have not previously alloimmunized. Dosing of RLYB212 will be initiated by gestational week 16 and continued at monthly intervals through pregnancy. An overview of the study's design is illustrated below.

Phase 2 Dose Confirmation Trial of RLYB212 in Expectant Mothers



Prospective FNAIT Natural History Alloimmunization Study

We have an ongoing prospective, non-interventional, multinational natural history study. This study is designed to screen up to 30,000 expectant mothers presenting at gestational week 10 to 14 prenatal visit

to determine the frequency of women at higher FNAIT risk among expectant mothers of different racial and ethnic characteristics, as well as the frequency of HPA-1a alloimmunization and pregnancy outcomes among these women. Subject to future discussions with regulatory authorities, we expect that data from this study will contribute to a control dataset for a future single-arm Phase 3 registrational clinical trial for RLYB212. An additional objective of the FNAIT natural history study is to operationalize de novo the laboratory screening test paradigm for FNAIT risk and generate FNAIT laboratory test performance data that we plan to use for future regulatory discussions. As of March 1, 2024 approximately 9,400 women have been screened in the study.

RLYB116 for the treatment of disorders due to complement dysregulation

RLYB116 is an inhibitor of complement component C5, a component of the complement pathway which plays a central role in innate immunity as well as shaping adaptive immune response. Dysregulation of the complement pathway has been implicated in the pathogenesis of a growing number of diseases, making it an attractive target for therapeutic intervention. Antibody inhibitors of C5 have been successfully developed to treat diseases caused by immune dysfunction, including PNH, aHUS, refractory gMG and relapsing NMOSD. RLYB116 includes an Affibody molecule, which is an antibody mimetic protein that has a much smaller molecular weight than a traditional antibody and may also be easier and less costly to produce. In contrast to C5-targeted antibody therapeutics that are administered intravenously, RLYB116 has the potential to be administered as a small volume subcutaneous injection. RLYB116 also includes an albumin binding domain, which may extend the half-life of the Affibody domain. In addition, amino acid substitutions that are part of RLYB116 are intended to enhance its stability. We view RLYB116 as a potential pipeline-in-a-product with disease areas under consideration including PNH, gMG and antiphospholipid syndrome. We believe RLYB116 can address significant unmet needs for patients with these diseases by providing a potential treatment that is more accessible and patient-friendly than existing marketed products, including by reducing the frequency and improving the route of administration.

Based on our team's experience studying and developing therapies targeting the complement system, we believe there are four important attributes that could support clinical and commercial success in the treatment of a broad range of patients suffering from complement-mediated diseases. These include a mechanism of action targeting terminal complement, the ability to produce rapid, complete and sustained inhibition of C5, a safety profile consistent with C5 antibodies currently approved for therapeutic use, and pricing flexibility to treat a broad range of complement-mediated diseases. We believe RLYB116 has the potential to demonstrate these attributes, and if so, could have a life-transforming impact on patients. Given our desire to conserve capital, we may seek a partner or access to non-dilutive financing to support future clinical development.

The complement system

The complement system includes over 30 proteins in plasma and on cell surfaces that support the body's adaptive or antibody-based immune system in the destruction of pathogenic bacteria. Complement proteins circulate in the blood in an inactive form prior to activation in response to infection. Activation occurs through a pathway of proteolytic cleavage events initiated by pathogen recognition and resulting in pathogen destruction. Three complement pathways that converge on C5 are known and are referred to as the classical, lectin and alternative pathways. In the classical pathway, antibodies bind to antigens, which in turn trigger a protease cascade that activates complement protein C3 and then complement protein C5. Activation of C5 convertase generates C5b which can initiate formation of membrane pores and subsequent lysis of cells. The binding of C5b to host cells is normally prevented by the presence of specific glycoproteins on the cell surface.

gMG disease background

gMG is a potentially life-threatening, rare autoimmune neuromuscular disorder. Patients with gMG develop antibodies that attack critical signaling proteins at the junction between nerve and muscle cells, thereby inhibiting the ability of nerves to communicate properly with muscles. This inhibition leads to muscle weakness, which can occur in ocular muscles leading to droopy eyelids as well as blurred or double vision, and can occur in the muscles in the face, neck, throat and jaw, causing difficulty chewing and swallowing as well as respiratory problems, speech difficulties and weakness in skeletal muscles leading to problems in limb function. While symptoms can be transient and remit spontaneously in the early stages of the disease, as the disease progresses, symptom-free periods become less frequent and disease exacerbations can last for months. Up to 20% of gMG patients experience respiratory crisis at least once in their lives. During such a crisis, a decline in respiratory function can become life-threatening and require intubation and mechanical ventilation. According to a comprehensive epidemiological study of

gMG in western Denmark from 1975-89, from the time of diagnosis, the overall survival rates at 3, 5, 10, and 20 years are estimated to be 85%, 81%, 69% and 63%, respectively. Patients with gMG suffer from poor quality of life due to the impact of their disease on physical function and the burden of treatment-related adverse events. The prevalence of gMG has been estimated to be at least 100 people per million.

Current treatments for gMG and their limitations

In the first-line setting, patients presenting with symptomatic gMG are commonly treated with acetylcholinesterase inhibitors such as pyridostigmine, to improve neuromuscular transmission. As the disease progresses, patients may receive immunosuppressive therapies off-label; unfortunately, these therapies are associated with a substantial treatment burden and can even lead to a worsening of the disease. Targeted, therapies approved for treatment of gMG include complement inhibitors (e.g., Soliris, Ultomiris, Zilbrysq) and FcRn inhibitors (e.g., Vyvgart, Rystiggo). These treatments have yielded substantial symptom improvements, though unmet need remains for treatments that are more patient-friendly. Rituximab is another treatment used off-label for gMG, though it is believed to have more benefit in patients with anti-muscle-specific tyrosine kinase ("MuSK") antibodies than those with anti-AChR antibodies.

For patients with severe gMG or recurrent exacerbation and crisis, there are a number of methods utilized to reduce circulating IgG antibodies. These procedures include plasma exchange and administration of IVIG. Both procedures are burdensome for patients and repeat administration is usually required to obtain significant reduction in symptoms. In addition, the large volumes of intravenous fluid associated with the administration of IVIG can lead to pulmonary edema and kidney complications.

Potential benefits of our approach

We are pursuing gMG as part of our initial development strategy for two reasons. First, complement overactivity is known to contribute to the disease pathophysiology of gMG, providing a sound biological rationale for a C5-targeted intervention. Second – and most importantly – our proprietary market research suggests that significant unmet need exists for more patient-friendly treatment options, which we believe could be addressed by RLYB116 as a once-weekly, small volume, self-administered subcutaneous therapeutic.

PNH disease background

PNH is a rare, potentially life-threatening hematologic disease characterized by complement-mediated destruction of red blood cells, or hemolysis. Early signs of PNH include hemoglobinuria, or dark colored urine, resulting from excretion of hemoglobin from lysed red blood cells, which is more prominent in the morning and decreases during the day. More serious symptoms of PNH include anemia, excessive weakness, fatigue, severe abdominal pain, severe headaches and recurrent infections. PNH leads to over a 60-fold increase in the risk of venous thromboembolism compared to the general population and these thrombotic events lead to between 40% and 67% of deaths in PNH patients. Approximately two thirds of patients with PNH develop chronic kidney disease ("CKD"), and kidney failure is the cause of death in 8% to 18% of patients with PNH. In the absence of disease-modifying treatment, PNH results in the death of approximately 35% of affected individuals within five years of diagnosis. The prevalence of PNH has been estimated to be approximately 12-13 people per million.

Current treatments for PNH and their limitations

The only curative treatment currently available for PNH is a stem cell transplant from a related donor. However, this procedure is associated with significant risk and is typically used only in those patients with severe disease, such as life-threatening thrombosis or dangerously low blood counts. Various supportive therapies include anticoagulants, red blood cell transfusions and supplements of iron and folate. These therapies provide some relief from symptoms but do not address the underlying cause of the disease.

There are currently four approved disease-modifying drugs for PNH. Although these drugs have meaningfully improved the lives of patients with PNH, they have limitations including sub-optimal delivery (three of the four are delivered intravenously or via subcutaneous infusion) and high cost that result in limitations on access to therapy. Despite these limitations, worldwide sales of these drugs exceeded $5 billion in 2022. We believe that a product that works through a similar mechanism but with weekly dosing and a low-volume, convenient route of administration and improved patient access has the opportunity to further transform PNH therapy for patients.

Potential benefits of our approach

We believe PNH represents an attractive development opportunity for RLYB116 for several reasons. First, PNH has a well-understood disease pathophysiology driven by complement, providing a sound biological

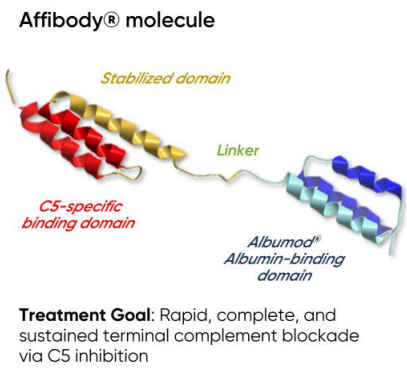
rationale for a C5-targeted intervention. Second, PNH offers the opportunity for early clinical validation using objective endpoints, including impact on lactate dehydrogenase, a component of red blood cells that is increased in circulation as a result of hemolysis. And third – and most importantly – we believe that with a patient-friendly and accessible therapy, RLYB116 could potentially provide transformative therapeutic impact for unserved and underserved patients with PNH globally.

Our solution: RLYB116

RLYB116 is an engineered protein that includes an Affibody molecule and an albumin binding domain. We acquired rights to RLYB116 from Swedish Orphan Biovitrum AB (Publ) ("Sobi"). RLYB116 was designed for optimal C5 binding, increased stability, as well as a long half-life in serum. Potential benefits of RLYB116 include:

- **Subcutaneous administration**. The low molecular weight allows for a higher concentration of active molecules than antibodies in an equivalent volume. This increases the probability of being able to deliver RLYB116 in a volume suitable for subcutaneous administration.
- **Efficiency of manufacturing**. RLYB116 is expressed in E coli, providing for a more streamlined and potentially lower cost manufacturing process compared to antibodies or other biologics expressed in mammalian cell culture, which typically require larger scale and longer manufacturing times.
- **Less frequent dosing**. Linkage of the Affibody domain to an albumin binding domain may lengthen the dosing interval of RLYB116 by extending the biological half-life.
- **Potentially lower risk of treatment conversion**. Due to 1:1 binding to C5, there is an expected lack of risk for drug-target-drug complex formation when switching from treatment with an antibody.
- **Favorable stability.** The Affibody platform provides the possibility of delivering highly stable and soluble therapeutic agents that allow for high-concentration low-volume products.

Affibody Scaffold and RLYB116 Structure

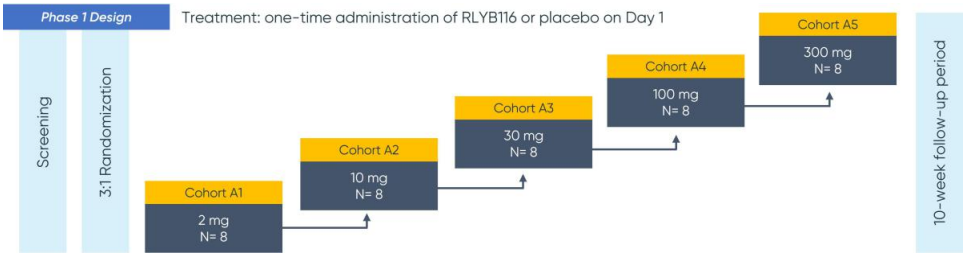


Clinical development of RLYB116

We have completed a Phase 1 clinical trial in healthy participants that included the study of RLYB116 as a SAD and a MAD.

The SAD design was a single-blind, placebo-controlled, dose escalation trial investigating the safety, PK and PD of single dose RLYB116 in healthy participants. The SAD portion of the Phase 1 trial included five sequential ascending dose cohorts with doses ranging from 2mg up to 300mg, each enrolling 8 subjects (6 treated with RLYB116 and 2 with placebo) with a 10 week post-treatment / safety follow-up period. An overview of the clinical trial's design is illustrated below.

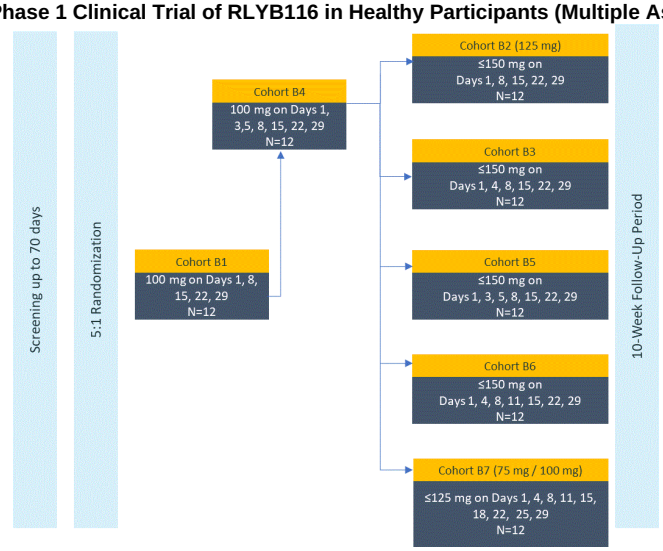
Design of the Phase 1 Clinical Trial of RLYB116 in Healthy Participants (Single Ascending Dose)



Data from the SAD portion of the trial showed consistent increases in exposure with increasing dose levels, low inter-subject variability, and a mean elimination half-life greater than 300 hours after a single SC, low volume injection. In the 100 mg dose group study participants that received RLYB116 (n=6) had a reduction in free C5 greater than 99% within 24 hours of dosing and RLYB116 was observed to be generally well-tolerated at this dose, with mild adverse events and no drug-related serious adverse events reported. Based on the data from the 100 mg dose and the volume of administration of the 300 mg dose, we elected to proceed with the 100 mg dose to initially evaluate multiple dose administration of RLYB116. Across the five single dose cohorts, adverse events were generally mild to moderate in severity with a dose-related increase in the frequency of gastrointestinal adverse events. There were no drug-related serious adverse events.

The MAD portion of the Phase 1 trial included an adaptive single-blind design with a 4-week treatment duration to evaluate the safety, tolerability, PK, and PD of RLYB116 with multiple dose SC administration. The MAD portion of the trial included four cohorts: Cohort 1 (weekly dosing of 100 mg), Cohort 2 (3 doses of 100 mg the first week followed by weekly dosing), Cohort 3 (150 mg weekly dosing reduced to 125 mg weekly dosing) and Cohort 4 (75 mg twice the first week followed by 100 mg twice per week) with post-treatment / study follow-up for 10 weeks.

Design of the Phase 1 Clinical Trial of RLYB116 in Healthy Participants (Multiple Ascending Dose)



In December 2023, we reported data from the MAD portion of the Phase 1 trial that demonstrated a 100 mg low volume (1 mL) once-weekly dose of subcutaneously administered RLYB116 achieved sustained mean reductions in free C5 of greater than 93%, including at day 29 with measurement prior to the last dose. The reduction in free C5 at 24 hours after the first dose of 100 mg was greater than 99%. In the MAD portion of the Phase 1 trial, RLYB116 also demonstrated low inter-subject variability and consistent increases in exposure

relative to dose with a mean estimated elimination half-life for RLYB116 of >300 hours. RLYB116 administered as a 100 mg once-weekly dose was also observed to be generally well tolerated. Across the MAD portion of the trial, injection site reaction (ISR) was the most common adverse event (all mild in severity) and gastrointestinal adverse events increased with increasing dose. There was one case of severe liver function test ("LFT") elevation in Cohort 3 in a participant with a history of hepatitis that resulted in discontinuation of treatment. Finally, the measurement of anti-drug antibody ("ADA") formation in the study did not demonstrate an effect on PK or PD parameters and did not appear to be associated with an effect on the severity or incidence of adverse events.

In December 2023, we announced that we would not immediately initiate a Phase 2 clinical trial of RLYB116 for the treatment of gMG, and would prioritize near-term program investments in the RLYB116 manufacturing process. We expect that the additional manufacturing work will improve tolerability at higher doses with a low injection volume and infrequent SC administration, which will enable higher exposure to RLYB116 and potentially increase C5 reduction. If successful, we believe the anticipated manufacturing enhancements will expand the opportunity to treat a broader range of complement-mediated diseases, including PNH and antiphospholipid syndrome. Based on market research conducted to date, we believe that an effective, once-weekly, well-tolerated therapy that can be rapidly self-administered with an autoinjector would be an attractive alternative for patients suffering from gMG and other complement mediated diseases.

RLYB114 for the treatment of ophthalmic disorders

RLYB114 is a C5-targeted Affibody molecule conjugated to polyethylene glycol ("PEG"). The addition of PEG to protein therapeutics is a well-established method of extending the half-life and reducing the immunogenicity of molecules in the body. Given the role of the complement system in retinal and ocular pathology, we believe that RLYB114 could be used to treat ophthalmic diseases, including inflammatory and degenerative disorders.

Potential role of complement in ocular diseases

Dysregulation of the complement system may drive ocular inflammation and contribute to vision loss in multiple diseases such as age-related macular degeneration ("AMD"). A number of genetic studies have shown links between alterations in genes encoding various complement factors and the risk of development of AMD. Several clinical trials of inhibitors of the complement pathway including C5 inhibitors have been conducted, with reports of modest efficacy. Reasons for this limited efficacy are unknown but could include the disease stage, level of intervention in the complement pathway, drug delivery mechanism and the ability of the therapeutic to cross Bruch’s membrane and the retinal pigment epithelium.

Our solution: RLYB114

In February 2023, we entered into a collaboration with EyePoint. We are evaluating RLYB114 with EyePoint’s proprietary technology for sustained intraocular drug delivery, with the initial focus on geographic atrophy, an advanced form of age-related macular degeneration that leads to irreversible vision loss. We and EyePoint expect to provide an update on this collaboration in the first half of 2024.

RLYB331 for the treatment of severe anemia with ineffective erythropoiesis and iron overload

In May 2022, we obtained worldwide exclusive rights to RLYB331, a preclinical antibody. We believe RLYB331 has the potential to address a significant unmet need for patients with severe anemias with ineffective erythropoiesis and iron overload, including beta thalassemia and a subset of lower risk myelodysplastic syndromes. Currently these patients are underserved by the existing standard of care.

RLYB331 is a monoclonal antibody that is designed to inhibit MTP-2. The inhibition of MTP-2 significantly increases levels of hepcidin, decreases iron load and treats ineffective erythropoiesis. We are continuing with preclinical activities to support the transition of this asset into clinical development and expect to report additional animal data from this program in the first half of 2024.

AI drug discovery collaboration with Exscientia

We established a partnership with Exscientia, an AI and machine learning drug discovery company. Our partnership currently consists of a joint venture that is focused on the discovery and development of small molecules for the treatment of patients with rare metabolic diseases. We are initially targeting ENPP1, an

enzyme involved in regulating extracellular levels of pyrophosphate, a natural inhibitor of calcium mineralization in bone formation, for the treatment of patients with HPP.

RE Ventures I, LLC : ENPP1 inhibitor program for the treatment of patients with HPP

We are developing an ENPP1 inhibitor for the treatment of patients with HPP, a rare, potentially life-threatening genetic disease characterized by mutations in the ALPL gene. These mutations lead to diminished activity of the tissue non-specific alkaline phosphatase ("TNSALP") enzyme and the accumulation of PPi, which inhibits bone mineralization causing multiple skeletal pathologies. ENPP1 is a Type II transmembrane glycoprotein that cleaves ATP, producing PPi, and is a major source of PPi production in cells. We believe that controlling inhibition of ENPP1 may reduce PPi levels and restore balance within the bone mineralization process.

HPP disease overview

HPP is an inherited disorder that affects the development of bones and teeth. The most severe forms of the disorder tend to occur before birth and in early infancy. Infants afflicted with the disorder have short limbs, an abnormally shaped chest, soft skull bones, poor feeding, failure to gain weight, respiratory complications and high levels of calcium in the blood, or hypercalcemia, which can lead to life-threatening complications. In other cases, the disease is not recognized until later in childhood where it manifests as rickets, pain, decreased mobility, deficits of growth and fractures. Children with less severe HPP can experience early loss of primary teeth and may have short stature with bowed legs or knock knees, enlarged wrist and ankle joints and an abnormal skull shape. Findings in adults include a softening of the bones, known as osteomalacia, and recurrent fractures in the foot and thigh bones that can lead to chronic pain. The incidence of HPP has been reported to be 1 in 100,000 (United States and Canada) to 1 in 300,000 (EU) for severe disease and 1 in 6,370 (EU) for less severe forms.

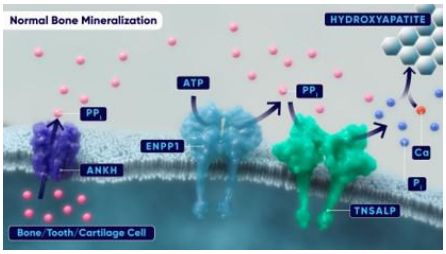
The various manifestations of HPP are caused by the combination of a lack of phosphate and an excess of PPi due to a deficiency of TNSALP, the enzyme that converts PPi to phosphate. This deficiency negatively impacts bone formation by reducing the hydrolysis of PPi to phosphate required for normal bone formation, resulting in a build-up of PPi, a potent inhibitor of mineralization.

Strensiq, an enzyme replacement therapy marketed by AstraZeneca plc ("AstraZeneca"), is the only approved therapy to treat patients with perinatal-, infantile-and juvenile-onset HPP. The therapy has been shown to lead to significant improvements in morbidity and mortality in patients with perinatal- and infantile-onset HPP, and improvements in morbidity for patients with juvenile-onset HPP. However, Strensiq has limitations, including its dosing regimen and patient access. Strensiq is administered by subcutaneous injection either three or six times per week using a weight-based dosing scale, which can be both onerous and painful for patients.

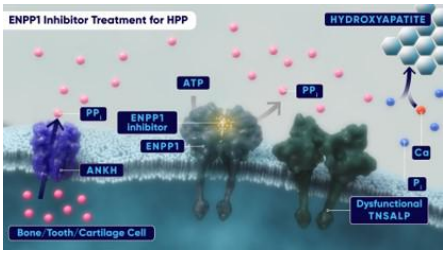
Our solution: an ENPP1 small molecule inhibitor

We are developing an orally available, small molecule ENPP1 inhibitor designed to reduce PPi levels through the controlled inhibition of ENPP1, which we hypothesize may restore the balance of PPi and phosphate needed to promote bone mineralization. We and Exscientia expect to select a small molecule development candidate to advance into clinical development. Proof of mechanism studies are in progress with a leading global HPP expert. We plan to provide an update on the progress of the program in the second half of 2024.

Scientific Rational: ENPP1 Inhibition for the Treatment of Hypophosphatasia



Under normal conditions, the level of PPi and Pi is kept in balance by activity of TNSALP, ENPP1 and ANKH. In patients with HPP, the reduction of PPi hydrolysis by TNSALP results in a relative increase in PPi, leading to an inhibition of mineralization, and inhibited hydroxyapatite formation.



Through controlled inhibition of ENPP1, we aim to reduce PPi and improve mineralization, restoring hydroxyapatite formation.

AbCellera Collaboration

We entered into a strategic alliance with AbCellera to discover, develop, and commercialize novel antibody-based therapeutics for rare diseases. This multi-year, multi-target collaboration combines AbCellera's antibody discovery engine with Rallybio's clinical and commercial expertise in rare diseases to identify optimal clinical candidates with a goal of delivering therapies to patients. AbCellera and Rallybio intend to co-develop up to five rare disease therapeutic targets, which will be chosen together by both companies. The partnership's first program is focused on addressing the significant unmet therapeutic needs of patients with rare metabolic diseases.

Competition

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. There are many public and private biopharmaceutical companies, universities, government agencies and other research organizations actively engaged in the research and development of products that may be like our product candidates or address similar markets. In addition, the number of companies seeking to develop and commercialize products and therapies competing with our product candidates is likely to increase. However, we seek to build our portfolio with key differentiating attributes to provide a competitive advantage in the markets we target. The success of our product candidates, if approved, is likely to be a result of their efficacy, safety, convenience, price, the level of biosimilar or generic competition and/or the availability of reimbursement from government and other third-party payors.

FNAIT. There are currently no approved therapies for the prevention or treatment of FNAIT. In one frequently used approach to manage pregnancies where the mother is known to have a history of FNAIT, physicians administer high levels of IVIG. Companies that currently market IVIG include ADMA Biologics, Bio Products Laboratory, CSL Behring, Grifols, Kedrion Biopharma, Leadiant Biosciences, Octapharma and Takeda Pharmaceutical Company Limited.

gMG. Very early-stage gMG is symptomatically treated by the use of acetylcholinesterase inhibitors such as pyridostigmine bromide, marketed as Mestinon by Bausch Health. Eculizumab and ravulizumab are also approved for the treatment of gMG in patients who are positive for anti-AChR antibodies. Efgartigimod, marketed as Vyvgart by Argenx SE, is a neonatal Fc receptor blocker also approved for the treatment of patients with generalized MG who are positive for anti-AChR antibodies and Zilbrysq, a macrocyclic peptide marketed by UCB Pharma was approved for the treatment of AChR+ adult patients with gMG. Rozanolixizumab, marketed as Rystiggo by UCB, is a neonatal Fc receptor blocker approved for the treatment of gMG in adult patients who are AChR+ or anti-MuSK antibody positive. There are several other companies developing assets in mid- to late-stage clinical development for the treatment of gMG using a variety of approaches and modalities. These companies include AstraZeneca, Horizon Therapeutics (acquired by Amgen Inc.) and Immunovant, Inc.

PNH. The only curative treatment currently available for PNH is a stem cell transplant from a related donor. However, this procedure is associated with significant risk and is used only in those patients with severe disease, such as life-threatening thrombosis or dangerously low blood counts. Various supportive therapies include anticoagulants, red blood cell transfusions and iron and folate supplements. These therapies provide some relief from symptoms but do not address the underlying cause of the disease. There are four approved

drugs for PNH: eculizumab, marketed by AstraZeneca as Soliris; ravulizumab, marketed by AstraZeneca as Ultomiris; pegcetacoplan, marketed by Apellis Pharmaceuticals as Empaveli, and iptacopan, marketed by Novartis AG as Fabhalta. Eculizumab and ravulizumab are antibodies that bind complement C5; pegcetacoplan is a pegylated pentadecapeptide that targets complement C3; and iptacopan is a small molecule that inhibits complement factor B. There are several companies in mid- to late-stage clinical trials developing treatments for PNH. These include Roche, AstraZeneca, and Alnylam Pharmaceuticals, Inc. among others.

HPP. There is one approved treatment for HPP, asfotase alfa, marketed by AstraZeneca as Strensiq, which is an alkaline phosphotase enzyme replacement therapy, and the only approved therapy for the treatment of perinatal-, infantile- and juvenile-onset HPP. AstraZeneca is developing a second generation enzyme replacement therapy, ALXN-1850 which is currently in clinical development, and Aruvant is developing ARU-2801, an AAV gene therapy currently in preclinical development. There are several companies pursuing ENPP1 small molecule inhibitors for the treatment of cancer, including Angarus Therapeutics, Avammune Therapeutics, Tcino Bioscience, Nanjing Zenshine Pharmaceuticals Co., Ltd. and Stingray Therapeutics, Inc. with all these companies in discovery or preclinical development. We are not aware of other small molecule inhibitors in development for the treatment of patients with HPP.

Many of our competitors may have significantly greater name recognition and financial, manufacturing, marketing, product development, technical, commercial infrastructure, and human resources than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Intellectual Property

Our success depends, in part, on our ability to obtain, maintain, defend, and enforce patent rights and other intellectual property rights that protect our business, preserve the confidentiality of our trade secrets, and operate without infringing the valid and enforceable intellectual property rights of others. In addition to our efforts to protect our product candidates and methods of using them, we also seek to secure or acquire patent rights regarding other products and methods that are important to the general development of commercial products. We utilize a multi-layered approach that includes acquiring intellectual property rights through purchase or exclusive license, filing and prosecuting U.S. and foreign patent applications directed to our own innovations, and developing and protecting proprietary know-how to maintain our competitive position.

Our ongoing efforts to secure patent rights that protect our business constitute a key component of our business strategy. We also strive to protect as trade secrets or confidential know-how, certain aspects of our programs and technological innovations that are commercially valuable but are not amenable to or appropriate for patent protection. We achieve this, in part, through the use of confidentiality agreements with our employees, consultants, scientific advisors, collaborators, licensors, and contractors, and by striving to maintain physical security of our premises and digital security of our electronic information and technology systems.

Notwithstanding our commitment to protecting our intellectual property rights, we, like other pharmaceutical and biopharmaceutical companies, are subject to several sources of uncertainty that can affect those rights. For example, we cannot be certain that any patents that we currently own or in-license, or that we may own or in-license in the future, will not be challenged, held to be invalid and/or unenforceable, have the scope of their claims narrowed, or be circumvented by others. Nor can we be certain that such patents will successfully protect our products or our business from competition.

Similarly, with respect to patent applications that are currently pending, or that may be pending in the future, we cannot be certain that such patent applications will result in the issuance of granted patents, or of patent claims with the desired claim scope. In order to secure an issued patent, an invention claimed in a patent application must meet certain legal requirements for patentability, which differ between countries based on each country's particular patent laws. In addition, because of the significant amount of time required for clinical development and regulatory review of product candidates, we cannot be certain that any of our product candidates will be commercialized while there is significant patent term remaining on patents relating to those products. The term of a patent depends upon the legal requirements for determination of patent term in the

country in which that patent is granted. In most countries, including the United States, the patent term is 20 years from the earliest claimed filing date of a non-provisional patent application. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment ("PTA") which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office ("USPTO") in examining and granting the patent. Likewise, a patent's term may be shortened if it is terminally disclaimed over an earlier-expiring patent with a common owner or inventor.

The term of a U.S. patent relating to an approved drug product may also be extended to compensate the patentee for delays due to the regulatory approval process. Such a patent term extension ("PTE") cannot exceed five years, and cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Furthermore, the term can be extended for only one patent applicable to each regulatory review period and only those claims covering the approved product, or a method for using it or manufacturing it, may be extended. In the future, if any of our product candidates receive approval by the FDA we expect to apply for PTE on any issued patents covering those products, depending upon the length of the clinical studies for each product and other factors. There can be no assurance that we will benefit from any PTE or favorable adjustments to the terms of any patents we currently own or in-license or that we may own or in-license in the future.

In addition to and separate from patent exclusivity, the FDA may also grant marketing exclusivity of varying lengths in connection with the approval of a New Chemical Entity (5 years), Biologic (12 years), or Orphan Drug indication (7 years). Marketing exclusivity may also be granted for new clinical studies (3 years) and pediatric studies (6 months) on approved drugs. Depending on the length of the regulatory approval process and the ability to make use of the procedures for obtaining PTE, any FDA exclusivity period may in part or in whole overlap with any patent exclusivity to which we are entitled. We intend to pursue relevant marketing exclusivities in the US and in foreign countries in which any candidate product is approved. However, we cannot be certain that any such exclusivities will be granted or, if granted, will insulate our commercial product(s) from competition.

With respect to trade secrets, while we have confidence in the protective measures that we employ, such measures can be breached, and we may not have adequate remedies for any such breach. We also cannot be certain that any of our activities will not be subject to the intellectual property rights of others.

As of March 1, 2024, we owned two patent families that were acquired from Prophylix AS ("Prophylix") and relate to the current product candidates in our FNAIT prevention program, RLYB211 and RLYB212. The acquired patent family covering RLYB212 and its use in treating and preventing FNAIT includes patents issued or accepted in Australia, Canada, Europe, Israel, Mexico, New Zealand, Russia, and the United States. A patent application in this family is pending in Brazil. The granted patents in this family will expire in 2035, excluding any PTA or PTE that may be awarded. The acquired patent family covering administration of RLYB211 for the prophylactic treatment of FNAIT includes patents issued in the United States, Europe and Canada. The foreign patents and one of the U.S. patents will expire at the end of 2026, while the other U.S. patent expires in November 2030 due to a PTA granted by the USPTO. We own three patent families directed to dosing and administration of RLYB212. Two of these families each include patent applications pending in Australia, Canada, Europe, Israel, Mexico, New Zealand, and the United States. Patents issuing in these two families will have an expiration date of June 2042, excluding any PTA or PTE that may be awarded. The third family is a pending United States provisional patent application. In addition, we filed and own two pending International (PCT) patent applications, one directed to assays for quantifying anti-HPA1a antibodies and the other directed to the formulation of RLYB212. We also exclusively in-license certain rights to technology from Versiti Blood Research Institute Foundation, Inc. pertaining to a mouse model of FNAIT.

As of March 1, 2024, we owned two patent families relating to the current product candidates in our complement program, RLYB114 and RLYB116, and certain aspects of their use that were acquired from Sobi. These two patent families currently include four granted U.S. patents and one pending U.S. patent application, with granted patents and/or pending patent applications in more than 25 additional countries worldwide. In the United States, Australia, Canada the European Patent Convention contracting states, and Japan, applications in both patent families have been granted and are scheduled to expire between 2033 and 2034, excluding any PTA or PTE. In addition, we filed and own a pending International (PCT) patent application directed to dosing and administration of RLYB116, and six pending provisional patent applications directed to methods of treatment of various C5-related conditions by administration of RLYB116. We have also non-exclusively in-licensed certain

patent rights relating to our current product candidates from Affibody, including patent rights relating to the Affibody molecule technology and Albumod albumin binding molecule technology.

As of March 1, 2024, we exclusively in-licensed from Kymab Limited certain patent rights to the current product candidate in our iron overload program, RLYB331, as well as back-up compounds. Under the exclusive license, we are managing prosecution of a patent family relating to RLYB331 and the back-up compounds. The patent family currently includes pending patent applications in the United States and in more than 20 other countries/regions, including Australia, Brazil, Canada, China, Eurasia, Europe, India, Japan, Mexico, and Saudi Arabia. In addition, we have non-exclusively in-licensed from Kymab Limited certain patent rights relating to the development, manufacture, and use of RLYB331 and the back-up compounds.

License Agreements

Product License Agreement with Affibody AB

In March 2019, our subsidiary IPC Research, LLC ("IPC Research") and Sobi entered into a Contract Assignment Agreement pursuant to which Sobi assigned to, and IPC Research assumed, all obligations in a certain Product License Agreement ("PLA") as amended, between Sobi and Affibody AB ("Affibody"), dated March 9, 2012, as amended on January 1, 2018 and December 22, 2020.

Pursuant to the PLA, we obtained a license to the Affibody platform technology and a particular albumin binding domain ("ABD"), in order to further develop and commercialize certain Affibody ligands, which we are now developing as RLYB116 and RLYB114.

Under the PLA, Affibody grants us (1) a non-exclusive right under certain patents to use the Affibody ligands alone or as a fusion protein and (2) an exclusive right to use the Affibody ligands alone or as a fusion protein, in each case, for human therapeutic use. Affibody also grants us (a) a non-exclusive right under certain patents to use the ABD in combination with the Affibody ligands as a fusion protein and (b) an exclusive right to use the ABD solely in combination with the Affibody ligands as a fusion protein, in each case, for human therapeutic use. Affibody grants us a non-exclusive license under applicable know-how needed to practice the rights and licenses granted under the PLA. All licenses to us are sublicensable, provided that each sublicense is consistent with the terms and conditions of the PLA. Under the PLA, Affibody has an exclusive right under any product patents, which are a category of certain patents that we own, to use the specific Affibody ligands outside of human therapeutics and a non-exclusive right under know-how needed to practice the Affibody ligands outside of human therapeutics.

Under the PLA, Affibody is the exclusive owner of, and controls prosecution, maintenance, and defense of intellectual property covering, platform technology. We are the exclusive owner of, and control prosecution, maintenance, and defense of intellectual property covering, product technology. Affibody agrees to disclose to us any improvement to the Affibody technology that it deems commercially reasonable for us to practice and grants us an option to license any such improvement. We have the first right to enforce product patents against a third-party infringer and Affibody retains the first right to enforce any other licensed patent. We agree to not provide or make available any Affibody Ligand to a third-party on a standalone basis except for research purposes or to commercialize a licensed product.

We agree to use commercially reasonable efforts to develop and commercialize a licensed product. We also will pay Affibody certain regulatory milestones up to an aggregate amount of €7.5 million and (a) a mid-single-digit royalty on annual net sales of products if such products are covered by a valid claim of a product patent or a platform patent or (b) low-single-digit royalties on annual net sales of products that are not covered by any such valid claim. Our obligation to pay royalties expires on a country-by-country and product-by-product basis on the later of (a) the expiration of the last-to-expire valid claim of a patent covering a licensed product or (b) the 10th anniversary following first commercial sale of such product in such country.

The PLA will terminate when we are no longer obligated to pay royalties to Affibody. Either party may terminate the PLA upon material breach of the PLA by the other, subject to a cure period, or immediately in the case of the other party's insolvency, bankruptcy or a similar event. Affibody may terminate the PLA immediately if we or any of our affiliates or third party transferees commences any proceeding challenging the validity of the licensed patents or any of Affibody's other patents or challenging the confidentiality or substance of the licensed know-how or licensed technology. We may terminate the PLA for convenience upon 90 days prior written notice and upon payment of any amounts due to Affibody through the effective date of such termination.

If Affibody terminates the PLA or if we terminate the PLA for convenience, (a) all rights and licenses granted under the PLA will terminate, (b) at Affibody's request, we must transfer all rights to the product technology free of charge to Affibody and (c) we must return or destroy all of Affibody's confidential information. Furthermore, if we terminate for convenience, we must grant Affibody an exclusive, royalty free perpetual right to use all regulatory filings, approvals and data provided to regulatory authorities in support of such filings or approvals that relate to the licensed product. However, if we terminate the PLA as a result of Affibody's material breach of the PLA or its insolvency or bankruptcy, we will retain our license and rights under the PLA, provided that we will remain bound by certain obligations under the PLA with respect milestone payments, royalties (subject to a reduction in rate, in the case of material breach), audits and indemnity.

Product License Agreement with Sanofi

In May 2022, through our subsidiary, Rallybio IPE, LLC ("Rallybio IPE"), we entered into a License Agreement with Kymab Limited ("Sanofi", and such agreement the "Sanofi License Agreement"). Under the Sanofi License Agreement, Sanofi provides Rallybio IPE with worldwide exclusive rights to Sanofi's KY1066, which is now referred to as RLYB331. Under the terms of the Sanofi License Agreement, Rallybio has an exclusive license to certain Sanofi patents to develop, manufacture and commercialize RLYB331 and Rallybio agrees to use commercially reasonable efforts to develop and commercialize a licensed product in at least one indication in the field in each of several major markets, as described in the Sanofi License Agreement.

We paid Sanofi an upfront cash payment of $3.0 million. In addition, Rallybio has agreed to pay Sanofi up to an aggregate of $43.0 million in development and regulatory milestones and up to an aggregate of $150.0 million in commercial milestones for a product in its first indication, plus tiered low-to-mid double digit percentages of such milestone amounts for up to three additional indications, and mid to high single digit royalties on net sales.

The Sanofi License Agreement contains other customary license terms including sublicensing, development, regulatory, manufacturing, commercialization, milestones, royalties, intellectual property, and termination. The Sanofi License Agreement will expire on a product-by-product and country-by-country basis at the end of the applicable royalty term. Either party may terminate the Sanofi License Agreement upon material breach of the Sanofi License Agreement by the other, subject to a cure period. Rallybio may terminate the Sanofi License Agreement for convenience upon 90 days prior written notice to Sanofi. Sanofi may terminate the Sanofi License Agreement immediately in the case of Rallybio's insolvency, bankruptcy or a similar event, or if Rallybio or its affiliates participates in any proceeding challenging the validity of the licensed patents.

If the Sanofi License Agreement is terminated in its entirety, among other things (a) all rights and licenses granted by Sanofi under the License Agreement (including any sublicenses) will terminate and (b) if Sanofi has an interest in developing, manufacturing and commercializing the licensed compounds or products, the parties to the Sanofi License Agreement shall negotiate an arrangement to provide Sanofi rights to the patents, know-how, materials and other properties controlled by Rallybio applicable to any of the licensed product.

Asset Purchase Agreements

Asset Transfer Agreement with Swedish Orphan Biovitrum AB (Publ)

In March 2019, through IPC Research, we entered into an agreement with Sobi, pursuant to which we acquired the right, title and interest in assets related to certain C5 inhibitor compounds. We are currently developing the assets acquired from Sobi as RLYB116 and RLYB114.

We paid Sobi an upfront purchase price of $5.0 million and we are obligated to pay Sobi an aggregate amount of up to $51.0 million upon achievement of certain development milestones and an aggregate amount of up to $65.0 million upon achievement of certain sales milestones.

We also will pay Sobi tiered, low single-digit royalties on annual net sales to third parties for products containing any compound transferred under the agreement as an active ingredient. Our obligation to pay royalties expires, on a country-by-country and product-by-product basis, on the later of (a) the 10th anniversary following first commercial sale of such product in such country and (b) the expiration date in such country of the last to expire of any issued patent included in the patent rights acquired from Sobi that includes at least one valid claim covering the sale of such product in such country.

We are obligated to use commercially reasonable efforts to research, develop and exploit at least one product that contains a compound transferred under the agreement as an active ingredient in each of the United States, EU and Japan.

If, prior to the commercial launch in the United States of the first product containing the compounds, we decide to divest our rights in the assets acquired from Sobi or to terminate all research, development and commercialization activities in respect of the acquired compounds, we must notify Sobi and negotiate in good faith with Sobi a possible business transaction relating to the assets. This right of negotiation will not apply to a transaction to sell all or substantially all of the assets of IPC Research or an affiliate of IPC Research, a pledge of the assets as collateral or a sale or transfer of the assets to an affiliate of IPC Research that agrees to be bound by the right of negotiation.

Asset Purchase Agreement with Prophylix

In June 2019, though our subsidiary Rallybio IPA, LLC ("Rallybio IPA"), we entered into an agreement with Prophylix to acquire all of Prophylix's rights, title and interest in, to and under all assets, properties and rights related to Prophylix's plasma-derived anti-HPA-1a immunoglobulin, and Prophylix's monoclonal antibody, which we are developing as RLYB212.

We paid Prophylix an upfront purchase price of approximately $1.2 million and reimbursed Prophylix approximately $1.8 million for certain manufacturing costs incurred by Prophylix. We are obligated to pay Prophylix an aggregate of up to $ 19.0 million upon achievement of certain development milestones and an aggregate of up to $20.0 million upon achievement of certain sales milestones.

We also will pay Prophylix tiered, mid-single-digit royalties on annual net sales of products containing the monoclonal antibody and tiered mid-to-high-single and low-double-digit royalties on annual net sales of products containing plasma-derived anti-HPA-1a immunoglobulin, subject to certain offsets for royalties payable under certain third-party licenses. Furthermore, the then-applicable royalty rate will be reduced by a mid-double digit percentage for the remaining royalty term on a country-by-country basis if it becomes reasonably likely that the Prophylix patents may no longer be enforceable in such country due to a challenge of the enforceability of the patents or the enforceability of the royalty payments following the expiration of all valid claims of the patents in such country. Our obligation to pay royalties terminates on a country-by-country and product-by-product basis on the later of (a) the expiration of the last-to-expire valid claim of a Prophylix patent covering a product, (b) expiration of regulatory exclusivity for the product in such country or (c) the 10th year anniversary following first commercial sale of such product in such country.

In the event the FDA grants a priority review voucher for one of our product candidates developed using the technology acquired from Prophylix, we will pay Prophylix either: (a) if we sell such priority review voucher to a third-party within 12 months of its receipt, a mid-double digit percentage of the proceeds we receive from the sale, net of taxes, or (b) if we do not sell the priority review voucher to a third-party within 12 months of receipt, a mid-double digit percentage of the fair market value of the priority review voucher as determined in accordance with the agreement.

We are obligated to use commercially reasonable efforts to develop and commercialize products containing plasma-derived anti-HPA-1a immunoglobulin in the United States and in at least one major European market. The agreement provides that if we provide notice to Prophylix that we determined that commercialization of products containing plasma-derived anti-HPA-1a immunoglobulin is not feasible due to an insufficient plasma supply following our continued and diligent efforts to obtain a sufficient plasma supply, then our obligation to develop products containing plasma-derived anti-HPA-1a immunoglobulin will cease, and we will be obligated to use commercially reasonable efforts to develop and commercialize products containing the monoclonal antibody in the United States and in at least one major European market.

If, after using commercially reasonable efforts to develop and commercialize products containing plasma-derived anti-HPA-1a immunoglobulin and the monoclonal antibody in the United States and in at least one major European market, we decide not to pursue any further development or commercialization activities for such products, then Prophylix will have the right to repurchase the remaining assets acquired under the agreement for approximately $1.2 million. Prophylix also will have the right to repurchase the remaining assets acquired under the agreement for approximately $1.2 million if we elect to transfer all or substantially all of the

assets acquired under the agreement to a third-party who does not agree to assume our obligations to develop and commercialize the products.

Joint Venture Agreement

In July 2019, we entered into a partnership with Exscientia and created RE Ventures I, LLC ("RE Ventures"), which is jointly owned by Exscientia and one of our wholly-owned subsidiaries, each a Member and collectively the Members. The joint venture was formed to initiate early-stage drug discovery of orally available small molecules targeting ENPP1 for the treatment of HPP, and thereafter for the future research, development, manufacture, sale and exploitation of any company-owned technology and compounds, including any resulting compound identified by the steering committee of the joint venture.

Under the RE Ventures operating agreement, we received a 50% interest in the joint venture in exchange for an initial contribution of £0.5 million ($0.6 million, based on the exchange rate at the time). RE Ventures used this initial capital to fund stage 1 of the ENPP1 program, and we committed to fund additional amounts if costs of stage 1 exceeded the initial funding. In June 2020, RE Ventures determined that the stage 1 objective of discovering compounds for ENPP1 with a certain potency had been achieved. In 2020, we contributed £ 1.1 million ($1.3 million, based on the exchange rate at the time) and in 2021, we contributed approximately £1.4 million ($2.0 million, based on the exchange rate at the time) to RE Ventures in support of ongoing Stage 2 development of the ENPP1 program. In 2022, we contributed £0.2 million ($0.3 million, based on the exchange rate at the time) and in 2023, we contributed £1.8 million ($2.3 million, based on the exchange rate at the time) to RE Ventures in support of ongoing development of the ENPP1 program. The board of managers of RE Ventures may determine from time to time that additional capital is necessary or appropriate to enable RE Ventures to conduct its activities, and may seek (but not require) additional capital contributions from the Members.

In the event that either Member does not fund a portion of committed additional amounts, the other Member may contribute the unfunded amount and the respective membership interests in RE Ventures will be adjusted accordingly.

A steering committee is responsible for oversight of RE Ventures' research and deployment plans as well as intellectual property and regulatory matters. A two-person board of managers manages the business and affairs of RE Ventures and is responsible for all management and other responsibilities not specifically reserved to the steering committee or to the Members. Each Member designates one member to the board.

Each Member is subject to customary restrictions on its transfer of interests in RE Ventures, including a right of first refusal, co-sale right and drag-along provision.

AbCellera Collaboration Agreement

In December 2022, the Company entered into a strategic alliance to discover, develop, and commercialize novel antibody-based therapeutics for rare diseases. This multi-year, multi-target collaboration will combine AbCellera’s antibody discovery engine with Rallybio’s clinical and commercial expertise in rare diseases to identify optimal clinical candidates and ultimately deliver therapies to patients.

Under the terms of the agreement, AbCellera and Rallybio will co-develop up to five rare disease therapeutic targets, which will be chosen together by both companies. The collaboration will allow Rallybio to add product candidates to its existing pipeline and also provides the option for AbCellera to conduct process development and clinical manufacturing activities. The partnership’s first program will focus on addressing the significant unmet therapeutic needs of patients with rare metabolic diseases.

Manufacturing and Supply

We do not own or operate, and currently have no plans to establish, any internal manufacturing facilities. We currently rely and expect to continue to rely on third-party contract manufacturer organizations ("CMOs") for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial production of any product candidates that are approved.

We currently rely on multiple CMOs for all of our preclinical and clinical supply requirements, including drug substances and drug products, and label and packaging for our preclinical research and clinical trials. We believe that we will be able to contract with other CMOs to manufacture drug substances if our existing sources

of drug substances were no longer available to us or with sufficient capacity, but there is no assurance that the drug substance capacity would be available from other CMOs on acceptable terms, on the timeframe that our business would require, or at all. We do not currently have supply commitments or other arrangements in place with our existing CMOs.

We do not have any current contractual relationships for the manufacture of commercial supplies of any of our product candidates if they are approved by the regulatory authorities, and we intend to enter into agreements with a CMO and one or more back-up manufacturers for the commercial production of our product candidates as they near phase 3 clinical trials.

Any products to be used in clinical trials and any approved product that we may commercialize will need to be manufactured in facilities, and by processes, that comply with the FDA's current Good Manufacturing Practice ("cGMP") requirements and comparable requirements of the regulatory agencies of other jurisdictions in which we are seeking approval. We currently employ internal resources to manage our CMOs. We believe that RLYB212, RLYB116, RLYB114, and RLYB331 can be manufactured through reliable and reproducible biologic and chemical processes from readily available starting materials. We believe that our manufacturing processes are amenable to scale-up and will not require unusual or expensive equipment. We expect to continue to develop, on our own or with our collaborators, product candidates that can be produced cost-effectively at contract manufacturing facilities.

We expect to rely on third parties for the manufacture of any in vitro diagnostic device, companion diagnostics or companion drug delivery systems we develop. For example, we have engaged a third-party to assist in developing laboratory screening tests and in our evaluation of potential companion diagnostics in conjunction with our development of RLYB212. Depending on the regulatory pathway and technology solutions we choose, we may engage third parties to continue the development and manufacturing of any device developed to support our therapeutic products.

Government Regulation

The research, development, testing, manufacture, quality control, packaging, labeling, storage, record-keeping, distribution, import, export, promotion, advertising, marketing, sale, pricing and reimbursement of drug and biologic products are extensively regulated by governmental authorities in the United States and other countries. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with compliance with applicable statutes and regulations and other regulatory requirements, both pre-approval and post-approval, require the expenditure of substantial time and financial resources. The regulatory requirements applicable to drug and biological product development, approval and marketing are subject to change, and regulations and administrative guidance often are revised or reinterpreted by the agencies in ways that may have a significant impact on our business.

U.S. Government Regulation of Drug and Biological Products

In the United States, the FDA regulates human drugs under the Federal Food, Drug, and Cosmetic Act, (the "FDCA"), and in the case of biologics, also under the Public Health Service Act (the "PHSA"), and their implementing regulations. Failure to comply with the applicable U.S. requirements may result in FDA refusal to approve pending New Drug Applications ("NDAs") or Biologics License Applications ("BLAs") or delays in development and may subject an applicant to administrative or judicial sanctions, such as issuance of warning letters, or the imposition of fines, civil penalties, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or civil or criminal prosecution brought by the FDA and the U.S. Department of Justice or other governmental entities.

The FDA must approve our product candidates for therapeutic indications before they may be marketed in the United States. For drug products, the FDA must approve an NDA, and for biologic products, the FDA must approve a BLA. An applicant seeking approval to market and distribute a new drug or biologic in the United States generally must satisfactorily complete each of the following steps:

- completion of preclinical laboratory tests and animal studies according to Good Laboratory Practice ("GLP") regulations or other applicable regulations;
- manufacture and testing of the therapeutic or biologic moiety and its respective product formulation according to cGMP regulations or other applicable regulations;

- submission to the FDA of an investigational new drug application ("IND"), which must become effective before human clinical trials may begin and must be updated annually and amended when certain changes are made;
- approval by an independent institutional review board ("IRB") or ethics committee representing each clinical trial site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practices ("GCPs") and other clinical-trial related regulations to evaluate the safety and efficacy of the investigational product for each proposed indication;
- preparation and submission to the FDA of an NDA or BLA requesting marketing approval for one or more proposed indications, including payment of application user fees;
- review of the NDA or BLA by an FDA advisory committee, where applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the drug or biologic and its respective finished product is produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of any FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data submitted in support of the NDA or BLA; and
- FDA review and approval of the NDA or BLA, which may be subject to additional post- approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy ("REMS") and any other potential post- approval studies required by the FDA.

Preclinical Studies and IND

Before testing any drug or biological product candidate in humans, the product candidate must undergo rigorous preclinical testing. The preclinical development stage generally involves laboratory evaluations of drug chemistry/biology, formulation, and stability, as well as in vitro and animal studies to assess safety and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety and toxicology studies. The sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND.

An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time, the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Imposition of a clinical hold could cause significant delays or difficulties in initiating and/or completing planned clinical trials in a timely manner. Certain long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may initiate or continue after an IND for an investigational product candidate is submitted to the FDA and human clinical trials have been initiated.

Human Clinical Trials in Support of an NDA or BLA

Clinical trials involve the administration of an investigational product candidate to healthy volunteers or patients with the disease to be treated under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, inclusion and exclusion criteria, dosing procedures and the parameters to be used in monitoring the safety and effectiveness criteria to be evaluated. Each protocol, as well as any subsequent amendments, must be submitted to the FDA as part of the IND.

An IRB representing each institution that is participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must thereafter conduct a continuing review of the trial. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors and the safety of human subjects. The IRB must review and approve, among other things, the trial protocol and informed consent information to be provided to clinical trial subjects or their legal representatives and must operate in compliance with FDA regulations.

Clinical trials must also comply with extensive GCP standards intended to ensure protection of human subjects and the quality and integrity of the study data, including requirements for obtaining subjects' informed consent. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group may recommend continuation of the trial as planned, changes in trial conduct or cessation of the trial at designated checkpoints

based on access to certain data from the study. The FDA may at any time while clinical trials are ongoing impose a partial or complete clinical hold based on concerns for patient safety and/or noncompliance with regulatory requirements. This order issued by the FDA would cause suspension of an ongoing trial until all outstanding concerns have been adequately addressed, and the FDA has notified the company that investigations may proceed.

Human clinical trials to evaluate therapeutic indications to support NDAs and BLAs for marketing approval are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The product candidate is initially introduced into human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution, and excretion, and if possible, to gain early evidence for effectiveness. Phase 1 trials may be conducted in healthy volunteers or, in the case of some products for severe or life-threatening diseases, including many rare diseases, the initial human testing is often conducted in patients with the target disease or condition.
- Phase 2: Clinical trials are conducted in a limited patient population with a specified disease or condition 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 to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3: Clinical trials are undertaken with an expanded patient population to further evaluate dosage, and to provide substantial evidence of clinical efficacy and safety in an expanded patient population, often at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product candidate and provide, if appropriate, an adequate basis for product labeling. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, to document a clinical benefit in the case of drugs or biologics approved under FDA’s accelerated approval regulations and to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA or BLA. Failure to exhibit due diligence with regard to conducting Phase 4 clinical trials could result in withdrawal of approval for the product.

The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients 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 clinical trial is not being conducted in accordance with the clinical protocol, GCP or other IRB requirements or if the drug has been associated with unexpected serious harm to patients.

Information about certain clinical trials, including details of the protocol and eventually study results, also must be submitted within specific time frames to the National Institutes of Health for public dissemination on the ClinicalTrials.gov data registry. Similar requirements for posting clinical trial information in clinical trial registries exist in the EU and in other countries outside the United States.

During the development of a new drug or biological product, sponsors have the opportunity to meet with the FDA at certain points, including prior to submission of an IND, at the end of phase 2 and before submission of an NDA or BLA. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date and for the FDA to provide advice on the next phase of development.

Concurrent with clinical trials, companies usually complete additional nonclinical studies and must also develop additional information about the physical characteristics of the drug or biological product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, potency and purity of the final drug or biological product. For biological products in particular, the PHSA

emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined in order to help ensure safety, purity and potency.

Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Marketing Application Submission and FDA Review

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, along with information relating to the product's chemistry, manufacturing, controls ("CMC") and proposed labeling, are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for one or more indications. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. The fee required for the submission of an NDA or BLA under the Prescription Drug User Fee Act ("PDUFA") is substantial (for example, for fiscal year 2024 this application fee is approximately $4.0 million), and the sponsor of an approved NDA or BLA is also subject to an annual program fee, currently more than $415,000 per program. These fees are typically adjusted annually, but exemptions and waivers may be available under certain circumstances. No user fee is required for orphan drug product applications, except when an application also includes an indication for a non-rare disease or condition.

The FDA conducts a preliminary review of all NDAs and BLAs within 60 days of receipt and informs the sponsor by the 74th day after the FDA's receipt of the submission whether an application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA or BLA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing.

After the submission is accepted for filing, the FDA begins an in-depth substantive review of the application. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months from the filing date in which to complete its initial review of a standard application and respond to the applicant and six months from the filing date for an application with priority review. The review process may be extended by the FDA for three additional months to consider new information or in the case of a clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission. Despite these review goals, it is not uncommon for FDA review of an NDA or BLA to extend beyond the PDUFA goal date.

Before approving an NDA or BLA, the FDA will typically conduct a pre-approval inspection of the manufacturing facilities for the therapeutic/biologic to determine whether the manufacturing processes and facilities comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities comply with cGMP requirements and are adequate to assure consistent production of the product within required specifications. The FDA also may inspect the sponsor and one or more clinical trial sites to assure compliance with GCP requirements and the integrity of the clinical data submitted to the FDA.

Additionally, the FDA may refer any NDA or BLA, including applications for novel product candidates which present difficult questions of safety or efficacy, to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations when making final decisions on approval. The FDA also may require submission of a REMS, if it determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks and to assure the safe use of the drug or biological product. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS and the FDA will not approve the NDA or BLA without a REMS.

Under the Pediatric Research Equity Act of 2003 ("PREA"), an NDA or BLA or certain supplements thereto must contain data that are adequate to assess the safety and effectiveness of the product 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, unless this requirement is waived, deferred or inapplicable. Sponsors must submit a pediatric study plan to FDA outlining the proposed pediatric study or

studies they plan to conduct, including study objectives and design, any deferral or waiver requests and other information required by regulation. The FDA must then review the information submitted, consult with the sponsor and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time. In general, PREA requirements do not apply to drugs or biologics for indications granted orphan drug designation by the FDA.

The FDA reviews an NDA or BLA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. The approval process is lengthy and often difficult, and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. After evaluating the application and all related information, including the advisory committee recommendations, if any, and inspection reports of manufacturing facilities and clinical trial sites, the FDA may issue either an approval letter or a Complete Response Letter ("CRL"). An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. The CRL may require additional clinical or other data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time- consuming requirements related to clinical trials, preclinical studies or manufacturing. If a CRL is issued, the applicant may either resubmit the NDA or BLA addressing all of the deficiencies identified in the letter or withdraw the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in response to an issued CRL in either two or six months depending on the type of information included. Even with the submission of this additional information, however, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

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

Regulation of Combination Products

Certain products may be comprised of components, such as drug or biologic components and device components that would normally be regulated under different types of regulations, and frequently by different centers at the FDA. These products are known as combination products. We expect to rely on a delivery system, such as pre-filled syringes, pen-injectors and/or autoinjectors to deliver certain of our product candidates. Although we have not yet selected the delivery system to use for administration of such product candidates, including RLYB212 and RLYB116, we expect that, if approved, any such product candidate would be regulated as a combination product, because it is composed of both a drug or biological product and a delivery system "device."

Under the FDCA and its implementing regulations, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The designation of a lead center generally eliminates the need to receive approvals from more than one FDA center for combination products, although the lead center may consult with other centers within the FDA. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a drug-device combination product is attributable to the drug product, the FDA center responsible for review of the drug product would have primary jurisdiction for the combination product.

A combination product involving a novel drug or biological product and delivery system generally would have a drug or biologic primary mode of action. A combination product with a drug or biologic primary mode of action would be reviewed and approved pursuant to the drug or biologic approval processes. In reviewing the NDA or

BLA for such a product, however, the FDA review division reviewing the application could consult with their counterparts in the device center to ensure that the device component of the combination product met applicable requirements regarding safety, effectiveness, durability and performance. Approval may require the performance of certain clinical studies, such as clinical usability or human factors studies to demonstrate the safety and/or effectiveness of the device component of the combination product.

Similar considerations apply to regulation of drugs combined with delivery systems outside the United States, including in the EU.

Expedited Programs for Serious Conditions

The FDA is authorized to designate certain products for expedited development or review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include fast track designation, breakthrough therapy designation, priority review designation and accelerated approval.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation provides opportunities for earlier and more frequent interactions with the FDA review team to expedite development and review of the product. The FDA also may review sections of the NDA or BLA for a fast track product on a rolling basis before the complete application is submitted if the sponsor and the FDA agree on a schedule for the submission of the application sections and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA. Fast track designation may be rescinded by the FDA if the designation is no longer supported by data emerging from the clinical trial process.

In addition, a new drug or biological product may be eligible for Breakthrough Therapy designation if it is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy designation provides all the features of Fast Track designation in addition to intensive guidance on an efficient development program beginning as early as Phase 1 and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate. Breakthrough designation may be rescinded by the FDA if the designation is no longer supported.

The FDA may designate a product for priority review if it is a drug or biologic that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines at the time that the marketing application is submitted, on a case-by-case basis, whether the proposed drug or biologic qualifies for priority review. Significant improvement over available therapies may be illustrated, for example, by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications and to shorten the FDA’s goal for taking action on a marketing application from ten months to six months for an original BLA or NDA from the date of filing.

Fast track designation, breakthrough therapy designation and priority review do not change the standards for approval and may not ultimately expedite the development or approval process.

Finally, the FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality ("IMM") and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. For drugs

granted accelerated approval, FDA generally requires sponsors to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. Failure to conduct required post-approval studies with due diligence, failure to confirm a clinical benefit during the post-approval studies, or dissemination of false or misleading promotional materials would allow the FDA to withdraw the product approval on an expedited basis. All promotional materials for product candidates approved under accelerated approval are subject to prior review by the FDA unless FDA informs the applicant otherwise.

Post-approval Requirements

Following approval of a new product, the manufacturer and the approved product are subject to pervasive and continuing regulation by the FDA, governing, among other things, monitoring and recordkeeping activities, reporting of adverse experiences with the product and product problems to the FDA, product sampling and distribution, manufacturing and promotion and advertising. Although physicians may prescribe legally available products for unapproved uses or patient populations (i.e., "off-label uses"), manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

If there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA/BLA or an NDA/BLA supplement, which may require the applicant to develop additional data or conduct additional preclinical studies and clinical trials. The FDA may also place other conditions on approvals including the requirement for a REMS to assure the safe use of the product, which may require substantial commitment of resources post-approval to ensure compliance. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that drug and biological products be manufactured in specific approved facilities and in accordance with cGMPs. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. The manufacturing facilities for our product candidates must meet cGMP requirements and satisfy the FDA or comparable foreign regulatory authorities' satisfaction before any product is approved and our commercial products can be manufactured. In addition, for any of our product candidates that include a device delivery system, the device component will be subject to aspects of the Quality System Regulation ("QSR) applicable to medical devices. Manufacturers of drug-device combination products may either opt to comply with all quality regulations governing each component of the product separately, or may take a "streamlined approach" to cGMP that allows the manufacturer to demonstrate compliance with the drug cGMPs along with compliance with several specific provisions from the device QSR—namely, management responsibility, design controls, purchasing controls, corrective and preventive action, installation, and servicing, as applicable.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations, including requirements for 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 are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. Future inspections by the FDA and other regulatory agencies may identify compliance issues at the facilities of our CMOs that may disrupt production or distribution or require substantial resources to correct. In addition, the discovery of conditions that violate these rules, including failure to conform to cGMPs, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA or BLA, including voluntary recall and regulatory sanctions as described below.

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

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about a product;
- mandated modification of promotional materials and labeling and issuance of corrective information;
- fines, warning letters, untitled letters or other enforcement-related letters or clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs/BLAs or supplements to approved NDAs/BLAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; or mandated modification of promotional materials and labeling and the issuance of corrective information.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act ("PDMA"), which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Additionally, the Drug Supply Chain Security Act ("DSCSA") imposes requirements related to identifying and tracing certain prescription drugs distributed in the United States, including most biological products.

U.S. Patent Term Restoration and Hatch-Waxman Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval for our product candidates, some of our 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. The Hatch Waxman Amendments permit restoration of the patent term up to five years as compensation for patent term lost during the FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date, and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. The patent-term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA or BLA plus the time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Regulatory exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application ("ANDA") or a 505(b)(2) NDA submitted by another company for another version of such drug. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The FDCA also provides three years of exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent for other conditions of use. Three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA

would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

In addition, both drugs and biologics can obtain pediatric exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or 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.

Biosimilars and Reference Product Exclusivity for Biological Products

In March 2010, the Patient Protection and Affordable Care Act was enacted in the United States and included the Biologics Price Competition and Innovation Act of 2009 (the "BPCIA"). The BPCIA amended the PHSA to create an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. To date, the FDA has approved a number of biosimilars. The FDA approved the first interchangeable biosimilar product in 2021 and has since approved others. The FDA has also issued several guidance documents outlining its approach to reviewing and approving biosimilars and interchangeable biosimilars.

Under the BPCIA, a manufacturer may submit an application that is “biosimilar to” or “interchangeable with” a previously approved biological product or “reference product.” In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product and (for products administered multiple times) that the biologic and the reference biologic 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 biologic. Upon licensure by the FDA, an interchangeable biosimilar may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

The biosimilar applicant must demonstrate that the product is biosimilar based on data from analytical studies showing that the biosimilar product is highly similar to the reference product, data from animal studies (including toxicity) and data from one or more clinical studies to demonstrate safety, purity and potency in one or more appropriate conditions of use for which the reference product is approved. In addition, the applicant must show that the biosimilar and reference products have the same mechanism of action for the conditions of use on the label, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity, and potency.

A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the first approved interchangeable biologic product will be granted an exclusivity period of up to one year after it is first commercially marketed. The FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product.

The BPCIA is complex and only beginning to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation and meaning of the BPCIA is subject to significant uncertainty.

Orphan Drug Designation and Exclusivity

Orphan drug designation in the United States is designed to encourage sponsors to develop products intended for the treatment of rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available for the disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation qualifies a company for certain tax credits. In addition, if a product candidate that has orphan drug designation subsequently receives the first FDA approval for that drug for the disease for which it

has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years following product approval unless the subsequent product candidate is demonstrated to be clinically superior. Absent a showing of clinical superiority, the FDA cannot approve the same product made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor or the sponsor is unable to provide sufficient quantities.

A sponsor may request orphan drug designation of a previously unapproved product or new orphan indication for an already marketed product. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete orphan disease designation application. To qualify for orphan exclusivity, however, the drug must be clinically superior to the previously approved product that is the same drug for the same condition. If a product designated as an orphan drug ultimately receives marketing approval for an indication broader than what was designated in its orphan drug application, it may not be entitled to exclusivity.

RLYB211 and RLYB212 have each been granted orphan drug designation by the FDA for the prevention of FNAIT.

Rare Pediatric Disease Designation and Priority Review Vouchers

In 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act requiring the FDA to award priority review vouchers to sponsors of certain rare pediatric disease product applications. This program is designed to encourage development of new drug and biological products for prevention and treatment of “rare pediatric diseases” by, upon initial approval of an application meeting certain specified criteria, providing companies with a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product receiving a priority review voucher may sell or otherwise transfer the voucher to another company. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted an application relying on the priority review voucher. The FDA may also revoke any rare pediatric disease priority review voucher if the rare pediatric disease product for which the voucher was awarded is not marketed in the United States within one year following the date of approval.

In order to receive a rare pediatric disease priority review voucher upon BLA or NDA approval, the product must receive designation from the FDA as a drug for a rare pediatric disease prior to submission of the marketing application. A “rare pediatric disease” is a disease that is serious or life-threatening, in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years and affects fewer than 200,000 people in the United States, or affects more than 200,000 people in the United States but there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug. In addition to receiving rare pediatric disease designation, in order to receive a rare pediatric disease priority review voucher, the NDA or BLA must be given priority review, rely on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population, not seek approval for a different adult indication in the original rare pediatric disease product application and be for a drug that does not include a previously approved active ingredient. In addition, under current statutory sunset provisions, even if a marketing application meets all of these requirements, FDA may only award a voucher prior to September 30, 2026 and only if the approved product received rare pediatric disease drug product designation prior to September 30, 2024.

RLYB211 and RLYB212 have each been granted rare pediatric disease designation by the FDA.

FDA Approval or Clearance of Companion Diagnostics

Under the FDCA, *in vitro* diagnostics, including companion diagnostics, are regulated as medical devices. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption applies, diagnostic tests require marketing clearance via 510(k) notification or approval via Premarket Approval (“PMA”) application from the FDA prior to commercial distribution.

In August 2014, the FDA issued final guidance clarifying the requirements that will apply to approval of therapeutic products and *in vitro* companion diagnostics. According to the guidance, for novel drugs and biologics, a companion diagnostic device and its corresponding therapeutic should be approved or cleared contemporaneously by the FDA for the use indicated in the therapeutic product's labeling.

Approval or clearance of the companion diagnostic device will ensure that the device has been adequately evaluated and has adequate performance characteristics in the intended population. In July 2016, the FDA issued a draft guidance intended to assist sponsors of the therapeutic products and *in vitro* companion diagnostic devices on issues related to co-development of the products.

The FDA previously has required *in vitro* companion diagnostics intended to select the patients who will respond to a product candidate to obtain PMA simultaneously with approval of the therapeutic product candidate. The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing, and labeling. PMA applications are subject to an application fee, which for fiscal year 2024 is approximately $483,000.

A clinical trial is typically required for a PMA application and, in some cases, the FDA may require a clinical study in support of a 510(k) submission. A manufacturer that wishes to conduct a clinical study involving the device is subject to the FDA's investigational device exemption ("IDE") regulation. The IDE regulations distinguish between significant and non-significant risk device studies and the procedures for obtaining approval to begin the study differ accordingly. Also, some types of studies are exempt from the IDE regulations. A significant risk device presents a potential for serious risk to the health, safety, or welfare of a subject. Significant risk devices are devices that are substantially important in diagnosing, curing, mitigating, or treating disease or in preventing impairment to human health. Studies of devices that pose a significant risk require both FDA and an IRB approval prior to initiation of a clinical study. Many companion diagnostics are considered significant risk devices due to their role in diagnosing a disease or condition. Non-significant risk devices are devices that do not pose a significant risk to the human subjects. A non-significant risk device study requires only IRB approval prior to initiation of a clinical study.

After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA. In the United States, device manufacturers are also subject to FDA's medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur, and FDA's correction and removal reporting regulations, which require that manufacturers report to the FDA corrections or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the QSR, which covers the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging, and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the United States.

Regulation Outside of the United States

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products outside of the United States. Whether or not we obtain FDA approval for a product candidate, we must obtain approval by the comparable regulatory authorities of foreign countries or economic areas, such as the 27-EU member states, before we may commence clinical trials or market products in those countries or areas.

Immediately following the UK's departure from the EU, in Great Britain (being England, Wales and Scotland), all medicinal products with a centralized EU marketing authorization were automatically converted to Great Britain marketing authorizations unless marketing authorization holders opted out of this process. According to Article 5(4) of Annex 2 to the Northern Ireland Protocol contained in the Agreement on the withdrawal of the UK

from the EU and the European Atomic Energy Community, c entralized marketing authorizations continue to apply in Northern Ireland. The post-Brexit restrictions on movements of goods including medicines have now been corrected by the “Windsor Framework”. Following the so-called “Windsor Framework” which is a political declaration by the European Commission and the Government of the UK of February 27 2023, from January 1 2025, all new medicines for the UK market, including Northern Ireland, will be authorized by the MHRA and UK packaging must carry a clearly legible ‘UK only’ to be allowed onto the UK market. For three years from January 1, 2021, the MHRA, the UK medicines regulator, may rely on a European Commission marketing authorization approval in the centralized procedure, i.e., the EC Decision Reliance Procedure (“ECDRP”), in order to expedite an application for a Great Britain marketing authorization. A separate application is still required, and marketing authorizations are granted by the MHRA. From January 1, 2024, the ECDRP was replaced by the new International Recognition Procedure (“IRP”). IRP is open to applicants that have already received an authorization for the same product from one of the MHRA’s specified reference regulators. IRP allows the MHRA to take into account the expertise and decision-making of trusted regulatory authorities to conduct targeted assessments of IRP applications while retaining the authority to reject applications if the evidence provided is considered insufficiently robust.

The EU and the UK have concluded a trade and cooperation agreement (“TCA”), which was provisionally applicable from January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of the outcomes of good manufacturing practice (“GMP”) inspections and applicants and marketing authorization holders may submit GMP certificates issued by the MHRA for sites located outside the EU/European Economic Area (“EEA”) as supporting information for EU regulatory submissions. However, the TCA does not foresee wholesale mutual recognition of UK and EU pharmaceutical regulations. Great Britain has also implemented EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the EU regulatory framework will continue to apply in Northern Ireland, which is the subject of ongoing negotiation between the UK Government and the European Commission). The regulatory regime in Great Britain currently broadly aligns with EU regulations. However, it is possible that these regimes may diverge in the future. It remains to be seen how Brexit will impact regulatory requirements for product candidates and products in the UK in the long-term.

With the exception of the EU EEA applying the harmonized regulatory rules for medicinal products, the approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly between countries and jurisdictions and can involve additional testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

European Union Drug Development, Review and Approval

In the EU, our product candidates will also be subject to extensive regulatory requirements. As in the United States, medicinal products can be marketed only if a marketing authorization is granted by a competent regulatory agency. Similar to the United States, the various phases of preclinical and clinical research in the EU are subject to significant regulatory controls.

The old regime, the EU Clinical Trials Directive 2001/20/EC (the “CTD”) has now been repealed and replaced by a new legislative framework provided by Regulation (EU) No 536/2014 (the “CTR”).

As of January 31, 2022, the CTR, came into application, and with it, the launch of the Clinical Trials Information System (“CTIS”), the centralized EU portal and database for clinical trials. The CTR is directly applicable in all EU Member States (and so does not require national implementing legislation in each EU Member State to give effect to the EU law instrument). The CTR has simplified the approval process for clinical trials to be carried out in the EU. Rather than applying for a clinical trial authorization in each EU Member State where the trial will be conducted, the CTR provides that one application be submitted centrally, via CTIS, which will then be reviewed by the designated NCA. If successful, the resulting decision arising from the evaluation process would cover all EU Member States concerned by the application. From January 31, 2023 all submissions of initial CTA applications for a new clinical trial must be made via CTIS. By January 31, 2025, all ongoing trials approved under the CTD must comply with the CTR and information relating to such clinical trials must be recorded in CTIS.

For any of our product candidates that incorporate a medical device to administer the medicinal product and are intended to be commercialized as a single integral product intended exclusively for use in the given combination and not usable separately, then the combination product is regulated by Directive 2001/83/EC or Regulation (EC) 726/2004 as a medicinal product. However, the medical device used for administration must satisfy the requirements for its general safety and performance under EU law governing general medical devices.

The EU regulatory regime currently provided under Directive 93/42/EEC (the "Medical Devices Directive") will be replaced by Regulation (EU) 2017/745 on medical devices (the "Medical Devices Regulation"). The Medical Devices Regulation came into application on May 26, 2021, subject to the transitional provisions for certain medical devices to remain on the EU market if they were certified under the Medical Devices Directive for a limited period. There are significant changes to the EU regulatory system governing medical devices under the Medical Devices Regulation.

Under the Medical Devices Regulation, data relating to the general safety and performance of the medical device must be contained in an application for marketing authorization for the combination product. Such information must be provided by the manufacturer of the medical device in its EU declaration of conformity or the relevant certificate issued by a notified body allowing the medical device manufacturer to affix a European Conformity (“CE”) mark to the medical device. If the dossier submitted to support the marketing authorization does not include the results of the conformity assessment or a CE certificate and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required in accordance with the Medical Devices Regulation, the medicinal products authority such as the EMA responsible for assessing applications for marketing authorization via the centralized procedure can require the applicant for a marketing authorization to provide an opinion on the conformity of the device part with the relevant general safety and performance requirements issued by a designated notified body.

By May 26, 2024, all manufacturers must comply with the Medical Devices Regulation. However, the EU legislature has extended the transitional periods, depending upon the risk classification of the medical device, e.g. December 31, 2027 for Class III devices and Class IIb implantable devices.

Under the EU regulatory regime, a company may submit marketing authorization applications under a centralized, decentralized or mutual recognition procedure. Where the product is intended to be marketed in one EU member state, a national application for a marketing authorization is filed. The centralized procedure is compulsory for medicinal products produced by biotechnology, designated orphan medicines, advanced-therapy medicines such as gene-therapies, and those medicinal products containing new active substances for specific indications such as the treatment of HIV, AIDS and immune dysfunctions, cancer, neurodegenerative diseases, diabetes, and viral diseases, and is optional for other medicines, which are highly innovative.

Centralized Procedure

Under the centralized procedure, a single marketing authorization application is submitted to the EMA where it will be evaluated by its advisory committee, the Committee for Medicinal Products for Human Use (the “CHMP”). A favorable CHMP opinion results in a single marketing authorization granted by the European Commission in an implementing decision, known as a centralized marketing authorization. A centralized marketing authorization is valid for all EU member states and, by extension (after taking the corresponding national implementing measures), in Norway, Iceland and Liechtenstein. In general, the initial marketing authorization is valid for five years, but once renewed is usually valid for an unlimited period, unless the European Commission decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Under the centralized procedure, the maximum timeframe for the evaluation of a marketing authorization application by the EMA is 210 days, excluding clock stops. Clock-stops allow the applicant the necessary time to provide additional information in response to questions raised by the CHMP. The clock-stops considerably extend the time taken by the CHMP to complete the evaluation of a marketing authorization application. Ordinarily, within 67 days of receipt of the positive scientific opinion provided by the EMA, the European Commission will issue a binding decision on granting of a centralized marketing authorization.

Decentralized Procedure

The decentralized procedure allows marketing authorization application in respect of medicinal products not authorized in the EU/EEA to be submitted simultaneously in two or more EU member states, whereas the

mutual recognition procedure must be used if the product has been authorized in at least one EU member state on a national basis, and the applicant seeks approval progressively of the same medicinal product in one or more EU member state(s). Both the decentralized and mutual recognition procedures provide for approval by one or more “concerned” member state(s) based on an assessment of an application performed by one “reference” member state. Under the decentralized approval procedure, an applicant submits an application, accompanied by a dossier, containing the requisite scientific data, and related materials to the reference member state and concerned member state(s). The reference member state prepares a draft assessment and drafts of the related materials within 120 days of the receipt of a valid application. Within 90 days of receiving the reference member state’s positive assessment report, each concerned member state must approve the assessment report and related materials, unless they identify a potential serious risk to public health.

Mutual Recognition Procedure

Under the mutual recognition procedure, the concerned member state(s) have a 90-day period to recognize the marketing authorization in the reference member state. The decentralized procedure contemplates a single clock-stop at day 105 for applicants to address questions raised by the reference member state and concerned member states, which may extend the process for completing the assessment procedure.

In either case, if there is a disagreement between member states during the assessment of the submitted data based on concerns about serious risks to public health, the Coordination Group for Mutual Recognition and Decentralized Procedures will consider the matter and seek to reach a conclusion within 60 days. If this is not possible, the reference member state can escalate the issue to the EMA for arbitration. The purely national procedure results in a marketing authorization in a single EU member state.

Conditional Marketing Authorization

In specific circumstances, E.U. legislation (Article 14–a Regulation (EC) No 726/2004 (as amended by Regulation (EU) 2019/5) and Commission Regulation (EC) No 507/2006 on Conditional Marketing Authorizations for Medicinal Products for Human Use) enables applicants to obtain a conditional marketing authorization prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional approvals may be granted for product candidates (including medicines designated as orphan medicinal products) if (1) the product candidate is intended for the treatment, prevention or medical diagnosis of seriously debilitating or life-threatening diseases; (2) the drug candidate is intended to meet unmet medical needs of patients; (3) a marketing authorization may be granted prior to submission of comprehensive clinical data provided that the benefit of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required; (4) the risk-benefit balance of the product candidate is positive, and (5) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data. A conditional marketing authorization requires specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and can be renewed annually, if the risk-benefit balance remains positive, and after a satisfactory assessment of benefit: risk balance and progress in fulfilling the specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization.

Pediatric Studies

In the EEA, companies developing a new medicinal product must agree upon a pediatric investigation plan (“PIP”), with the EMA’s Pediatric Committee (“PDCO”) and must conduct pediatric clinical trials in accordance with that PIP, unless a waiver applies. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which a marketing authorization is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults or other age groups not covered by the agreed PIP. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO in circumstances where the medicinal product or the product class is likely to be ineffective or unsafe in part or all of the pediatric population; or the disease or condition occurs only in adult populations, or the specific medicinal product does not represent a significant therapeutic benefit over existing treatments in pediatric patients. Products that are granted a marketing authorization with the results of the pediatric clinical trials conducted in accordance with the PIP (even where such results are negative) are eligible for six months’ supplementary protection certificate extension. In the case of orphan medicinal products, a two-year extension of the orphan market exclusivity may be available. This pediatric reward is subject to the condition that the results are provided in respect of all studies in compliance with the agreed PIP and is not automatically available.

European Union Regulatory Data Exclusivity

In the EU, new products, which are considered as referenced medicinal products, authorized for marketing qualify for eight years of data exclusivity and an additional two years of marketing exclusivity upon grants of a marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The marketing exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial authorization of the reference medicinal product in the EU. The ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

European Union Orphan Designation and Exclusivity

The criteria for designating an orphan medicinal product in the EU are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life- threatening or chronically debilitating condition, (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition. The term ‘significant benefit’ is defined in Regulation (EC) 847/2000 to mean a clinically relevant advantage or a major contribution to patient care.

Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. During this ten-year market exclusivity period, the EMA or the competent authorities of the Member States of the EEA, cannot accept an application for a marketing authorization for a similar medicinal product for the same indication. A similar medicinal product is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The application for orphan designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity in the EU may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the applicant consents to a second orphan medicinal product application; or
- the applicant cannot supply enough orphan medicinal product.

Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

An equivalent regime is reflected in domestic law in the UK. Under the UK regime, however, orphan designations are not granted and instead a decision is made at the point of marketing authorization grant.

RLYB211 and RLYB212 have each been granted orphan drug designation by the EMA for the prevention of FNAIT.

Priority Medicines Designation

The EMA grants access to the Priority Medicines ("PRIME") program to investigational medicines for which it determines there to be preliminary data available showing the potential to address an unmet medical need and bring a major therapeutic advantage to patients. As part of the program, EMA provides early and enhanced dialogue and support to optimize the development of eligible medicines and speed up their evaluation, aiming to bring promising treatments to patients sooner. Rallybio anticipates that it will request PRIME designation for certain of our product candidates.

Periods of Authorization and Renewals

A marketing authorization is valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least nine months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is generally valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal.

Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause).

Rest of the World Regulation

For other countries outside of the EU and the United States, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from jurisdiction to jurisdiction. Additionally, the clinical trials must be conducted in accordance with cGCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

Coverage, Pricing and Reimbursement

Sales of any biopharmaceutical products, if and when approved by the FDA or analogous authorities outside the United States, will depend in significant part on the availability of third-party coverage and reimbursement for the products.

In the United States, third-party payors include government healthcare programs, such as Medicare and Medicaid, private health insurers, managed care plans and other organizations. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services, including biopharmaceutical products. Significant uncertainty exists regarding coverage and reimbursement for newly approved healthcare products. Coverage does not ensure adequate reimbursement. It is time consuming and expensive to seek coverage and reimbursement from third-party payors. We may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA regulatory approvals. Third-party payors may take into account clinical practice guidelines in determining coverage and there may be significant delays before our products are addressed by such guidelines and we cannot predict what position such guidelines would take with respect to our products if and when addressed. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication, or utilize other mechanisms to manage utilization (such as requiring prior authorization for coverage for a product for use in a particular patient). Limits on coverage may impact demand for our products. Even if coverage is obtained, third-party reimbursement may not be adequate to allow us to sell our products on a competitive and profitable basis. As a result, we may not be able to maintain price levels high enough to realize an appropriate return on investment in product development.

In addition, 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. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed.

Some countries may require the completion of additional studies that compare the cost-effectiveness of our product candidate to currently available therapies (so called health technology assessment ("HTA") in order to obtain reimbursement or pricing approval). For example, subject to the requirements set out in Directive 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems, EU Member States have the legal competence to set national measures of an economic nature on the marketing of medicinal products in order to control public health expenditure on such products. Accordingly, EU Member States can 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. An EU 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. Other EU Member States allow companies to fix their own prices for drug products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. 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 products. Historically, products launched in the EU do not follow price structures of the United States and generally tend to be significantly lower.

Regulation (EU) 2021/2282 on health technology assessment (the “HTA Regulation”) entered into force on January 11, 2022 and will apply from January 12, 2025. Given the increasing use of health technology assessment (“HTA”) to guide market access in EU member states, the HTA Regulation seeks to achieve three legislative objectives: to promote convergence in HTA tools, procedures and methodologies; to ensure efficient use of resources and strengthen the quality of HTA across the EU and to improve business predictability. From January 15, 2025, all new oncology medicines and advanced therapy medicinal products (i.e. gene and cell therapies and tissue engineered products) will be assessed at EU level through the Joint Clinical Assessment procedure (“JCA”), which is part of an HTA to evaluate the relative clinical effectiveness of a new health technology against one or more other health technologies. From January 13, 2028, all new orphan medicinal products will be subject to JCA. From January 13, 2030, all new medicines will come under the scope of the HTA Regulation. The HTA Regulation established the Coordination Group on HTA (the “HTACG”) consisting of representatives of EU member states, mainly from HTA authorities or bodies. The HTACG’s remit is to coordinate and adopt the joint HTA work carried out by its subgroups within the scope of the HTA Regulation and to adopt methodological and procedural guidance documents for joint work, including JCAs.

The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic, and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States and parallel import or distribution (arbitrage between low-priced and high-priced member states) can further reduce prices. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Other U.S. Health Care Laws and Regulations

In the United States, biopharmaceutical manufacturers and their products are subject to extensive regulation at the federal and state level, such as laws intended to prevent fraud and abuse in the healthcare industry. These laws, some of which will apply only if and when we have an approved product, include:

- federal false claims, false statements and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid;
- federal healthcare program anti-kickback law, which prohibits, among other things, persons from offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for, or the purchasing or ordering of, a good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- FDCA, which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing such products prior to approval or for off-label use and regulates the distribution of samples;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- federal Open Payments (or federal “sunshine” law), which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with certain healthcare providers to the Centers for Medicare & Medicaid Services within the U.S. Department of Health and Human Services ("CMS") for re-disclosure to the public, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous state laws and regulations, including: state anti-kickback and false claims laws; state laws requiring pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers or report information related to payments to health care providers, marketing expenditures or drug prices; and state laws governing privacy, security and breaches of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- laws and regulations prohibiting bribery and corruption, such as the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "FCPA") which, among other things, prohibits U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations or foreign government-owned or affiliated entities, candidates for foreign public office, and foreign political parties or officials thereof.

Ensuring compliance is time consuming and costly. Violations of the laws may be subject to criminal and/or civil sanctions, including, in some instances, exclusion from participation in federal and state health care programs, which could adversely affect our business, financial condition, results of operations, and prospects.

Similar healthcare laws and regulations exist in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of personal information.

Health Care Reform in the United States and Potential Changes to Health Care Laws

Health care reform has been a significant trend in the U.S. health care industry and elsewhere. In particular, government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services. Health care reform, specifically reform addressing pricing and payment for drugs, was a focus of the Trump administration and remains a focus of the Biden administration. A number of healthcare reforms involving drugs have been successfully implemented, including reforms related to Medicare payment for drugs and manufacturer rebate obligations under the Medicaid Drug Rebate Program.

There has been heightened governmental scrutiny in recent years over the manner in which manufacturers set prices for their marketed products, which has resulted in proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing and reform government program reimbursement methodologies for pharmaceutical and biologic products. At the state level, individual states are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional federal and state health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services.

For a more detailed discussion of health care reform in the U.S., see “Risk Factors—Risks Related to Healthcare Laws and Other Legal Compliance Matters.”

Data Privacy Regulation

U.S. Privacy Law

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information, including laws requiring the safeguarding of personal information and laws requiring notification to governmental authorities and data subjects as well as remediation in the event of a data breach.

There have been several developments in recent years with respect to U.S. state data privacy laws. In 2018, California passed into law the California Consumer Privacy Act which took effect on January 1, 2020 and was expanded by the California Privacy Rights Act, which took effect on January 1, 2023, and which, collectively, imposed many requirements on businesses that process the personal information of California residents (collectively, “CCPA”). Many of the CCPA’s requirements are similar to those found in the General Data Protection Regulation (the "GDPR"), including requiring businesses to provide notice to data subjects regarding the personal information collected about them and how such information is used, shared, and retained, requiring that use, retention and sharing of personal information be reasonably necessary and proportionate to the purposes of collection or processing, providing data subjects the rights, in certain circumstances, to (i) request access to such personal information; (ii) request the erasure of such personal information; (iii) opt-out of “sales” of their personal information, (iv) opt-out of the “sharing” of their personal information (*i.e.*, disclosing for cross-context behavioral advertising), and (v) limit the use and disclosure of their “sensitive personal information” for purposes other than those for which it was collected. The CCPA contains significant penalties for companies that violate its requirements. It also provides California residents a private right of action, including the ability to seek statutory damages, in the event of a breach involving their personal information. Compliance with the CCPA is a rigorous and time-intensive process. Similar laws have been proposed or passed in more than half of the states in the United States and in the U.S. Congress, reflecting a trend toward more stringent privacy legislation in the United States. Compliance with evolving U.S. privacy and security laws, requirements and regulations may result in cost increases due to necessary systems changes, new limitations or constraints on our business models and the development of new administrative processes.

GDPR

Many countries outside of the United States maintain rigorous laws governing the privacy and security of personal information. For example, the collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the EEA, and the processing of personal data that takes place in the EEA, is subject to the GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, and it imposes heightened requirements on companies that process health and other sensitive data, such as requiring in many situations that a company obtain the consent of the individuals to whom the sensitive personal data relate before processing such data. Examples of obligations imposed by the GDPR on companies processing personal data that fall within the scope of the GDPR include providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, appointing a data protection officer, providing notification of data breaches and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million, or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR is a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance. On June 4, 2021, the European Commission released two revised sets of standard contractual clauses, which have been designed in part to assist organizations in meeting the requirement of the CJEU’s judgment. However, it is unclear how the use of these clauses will be scrutinized and enforced by supervisory authorities and privacy interest groups, and the process of entering into agreements with new standard contractual clauses, and updating our existing agreements that contain the previous clauses, may lead to additional costs and increase our overall risk exposure. Following the withdrawal of the U.K. from the EU, the U.K. Data Protection Act 2018 applies to the processing of personal data that takes place in the

U.K. and includes parallel obligations to those set forth by GDPR. Other countries maintain different privacy laws that we are subject to which may further increase our costs of compliance and expose us to greater legal risk.

Employees and Human Capital Resources

Our employees are driven by our mission to identify and accelerate the development of transformative therapies for patients with rare disorders. We believe that our deep commitment to high ethical and professional standards is fundamental to our mission, and we are determined to build a culture that values diversity, inclusiveness and equity, and empowers a skilled and experienced workforce to perform at the highest levels. We commit our resources and make investments, including through recruiting, training and collaboration, to promote the culture that we desire, and we expect our employees to embrace the Company's values and culture in all that we do.

As of December 31, 2023, we employed 43 full-time employees. Of our full-time employees, 22 employees are engaged in new product sourcing through business development, research, manufacturing, product development and clinical development, and 21 are engaged in executive, finance, human resources, legal and other administrative functions. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Corporate Information

Rallybio Holdings, LLC ("Rallybio Holdings") was formed in Delaware in March 2018 and Rallybio IPD, LLC was formed in Delaware in May 2020. On June 30, 2021, Rallybio IPD, LLC was converted into a Delaware corporation and changed its name to Rallybio Corporation.

Our principal executive offices are located at 234 Church Street, Suite 1020, New Haven, CT 06510 and our telephone number is (203) 859-3820. Our corporate website address is https://www.rallybio.com. Information contained on or accessible through our website is not incorporated by reference into this report and you should not consider information contained on or accessible through our website to be part of this report.

Available Information

Our Internet address is www.rallybio.com. Our website and the information contained on, or that can be accessed through, the website will not be deemed to be incorporated by reference in, and are not considered part of, this Annual Report on Form 10-K. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, proxy and information statements and amendments to those reports filed or furnished pursuant to Sections 13(a), 14, and 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") are available through the "Investors" portion of our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission ("SEC"). In addition, our filings with the SEC may be accessed through the SEC's Interactive Data Electronic Applications system at http://www.sec.gov. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Item 1A. Risk Factors.

You should carefully consider the risks and uncertainties described below together with all of the other information contained in this Annual Report on Form 10-K, including our financial statements and related notes appearing in this Annual Report on Form 10-K and the section of this Annual Report on Form 10-K titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." Negative consequences from these risks could harm our business, prospects, operating results and financial condition or cause the trading price of our common stock to decline. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business. See "Cautionary Note Regarding Forward-Looking Statements."

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the foreseeable future. We have not commercialized any products and have never generated revenue from the commercialization of any product. We are not currently profitable, and we may never achieve or sustain profitability.

We are a clinical-stage biotechnology company with a limited operating history. As a result, we are not profitable and have incurred significant losses since our formation. We had net losses of $74.6 million and $66.7 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $235.2 million. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to gain regulatory approval and become commercially viable. Since inception, we have devoted substantially all of our resources to raising capital, organizing and staffing the Company, business planning, conducting discovery and research activities, acquiring or discovering product candidates, establishing and protecting our intellectual property portfolio, developing and progressing our product candidates and preparing for clinical trials and establishing arrangements with third parties for the manufacture of our product candidates and component materials, including activities relating to our preclinical development and manufacturing activities for each of our programs and our Phase 1 clinical trials for RLYB212 and RLYB116, and planned Phase 2 clinical trial for RLYB212. We do not have any product candidates approved for sale and have not generated any revenue from product sales.

We expect to incur significant additional operating losses in the foreseeable future as we advance our programs and operate our business. The costs of advancing product candidates through each clinical phase tend to increase substantially over the duration of the clinical development process. The total costs to advance any product candidate to marketing approval in even a single jurisdiction are substantial. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to begin generating revenue from the commercialization of any product candidates or achieve or maintain profitability. Our expenses will increase substantially if and as we:

- advance our planned Phase 2 clinical trial for RLYB212, our lead product candidate for our FNAIT program;
- advance our FNAIT natural history study, and any other studies to support our development program and related regulatory submissions for RLYB212;
- plan for and conduct any future clinical trials for RLYB116 and any of our other product candidates;
- seek regulatory approvals for RLYB212, RLYB116 and any other product candidates, as well as for any related companion diagnostic, if required;
- advance our discovery and preclinical development activities for our product candidates;
- continue to discover and develop additional product candidates;
- hire additional clinical, scientific, and commercial personnel;
- acquire or in-license other product candidates or technologies;
- maintain, expand, and protect our intellectual property portfolio;
- secure manufacturing sources and supply chain capacity sufficient to produce adequate quantities of our product candidates, including any product candidate for which we obtain regulatory approval; and
- establish a sales, marketing, and distribution infrastructure to commercialize our programs, if approved, and for any other product candidates for which we may obtain marketing approval.

We do not know when or whether we will become profitable. Our ability to generate revenue and become profitable depends upon our ability to successfully complete the development of our product candidates and to obtain the necessary regulatory approvals for their commercialization, which is subject to substantial additional risks and uncertainties, as described under "— Risks Related to Discovery, Development, Clinical Testing, Manufacturing, and Regulatory Approval."

Each of our product candidates will require additional preclinical and/or clinical development, regulatory approval in multiple jurisdictions, the securing of manufacturing supply, capacity, distribution channels and expertise, the use of external vendors, the building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenue from product sales. As a result, we expect to continue to incur net losses and negative cash flows in the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. The amount of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If we are unable to develop and commercialize one or more product candidates, either alone or through current or future collaborations, or if revenues from any product that receives marketing approval are insufficient, we will not achieve profitability. Even if we successfully commercialize RLYB212, RLYB116 or any of our other product candidates, we may continue to incur substantial research and development and other expenses to identify and develop other product candidates. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis or meet outside expectations for our profitability. Our failure to become and remain profitable would decrease the value of the Company and could impair our ability to raise capital, maintain our research and development efforts, expand our business, execute our business plan or continue our operations.

We will require significant additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of RLYB212, RLYB116 or any additional product candidates we may develop.
We expect to spend significant amounts of capital to complete the development of, seek regulatory approvals for and, if approved, commercialize RLYB212 and RLYB116 or any of our other product candidates. In addition, we are obligated to make certain payments under our agreements with AbCellera, Affibody, Prophylix, Sobi, and Sanofi, including milestone and royalty payments in connection with achievement of certain development and commercial milestones as well as the sale of resulting products under such agreements. We may also spend significant capital to develop laboratory tests, and if required by the FDA or other healthcare agencies, one or more companion diagnostics, to identify patients for inclusion in our clinical trials or who are likely to respond to our product candidates.

Based upon our current operating plan, we believe that our existing cash, cash equivalents and marketable securities as of December 31, 2023, will be sufficient to fund our operating expenses and capital expenditure requirements into the middle of 2026. This estimate and our expectation to advance the preclinical and clinical development of RLYB212, RLYB116, and any other product candidates are based on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect, or our clinical trials may be more expensive, time consuming or difficult to design or implement than we currently anticipate. Changing circumstances, including any unanticipated expenses, could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more than currently expected because of circumstances beyond our control. Because of the numerous risks and uncertainties, the length of time and scope of activities associated with development of RLYB212, RLYB116 or any product candidate we may develop is highly uncertain, we are unable to estimate the actual amount of funds we will require for development, approval and any approved marketing and commercialization activities. Our future capital requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of our clinical trials through all phases of development;
- the identification, assessment, acquisition and/or development of additional research programs and additional product candidates;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, EMA, and other comparable foreign regulatory authorities, including any regulatory designations allowing for

priority review and any additional clinical trials required by the FDA, EMA or other comparable foreign regulatory authorities;

- the willingness of the FDA, EMA and other comparable foreign regulatory authorities to accept our clinical trial designs, as well as data from our completed and planned preclinical studies and clinical trials, as the basis for review and approval of RLYB212, RLYB116 and any other product candidates;
- the cost and timing of the manufacture and supply of non-clinical and clinical trial material for RLYB212, RLYB116 and our other product candidates;
- the progress, timing and costs of the development by us or third parties of companion diagnostics, if required, for RLYB212 or any other product candidates, including design, manufacturing and regulatory approval;
- the cost of filing, prosecuting, and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us;
- the costs associated with potential clinical trial liability or product liability claims, including the costs associated with obtaining insurance against such claims and with defending against such claims;
- the effect of competing technological and market developments;
- the cost of making royalty, milestone or other payments under our current or any future in-license agreements;
- our ability to maintain our collaborations with Exscientia and AbCellera on favorable terms and establish new collaborations;
- the extent to which we in-license or acquire additional product candidates or technologies; and
- the costs of operating as a public company.

We will require significant additional capital to advance the development and potential commercialization of our product candidates, which we may raise through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. Depending on our business performance, the economic climate and market conditions, we may be unable to raise additional funds when needed on acceptable terms, or at all. Moreover, uncertain geopolitical events, such as the war in Ukraine and conflict in Israel, have impacted the global economy, and a severe or prolonged economic downturn could result in a variety of challenges for our business, including disruptions in the financial markets, which could adversely impact our ability to raise additional capital when needed or on acceptable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we may need to significantly delay, scale back or discontinue the development of one or more of our product candidates or the commercialization of any product that may be approved for marketing, and we could be forced to discontinue operations. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts.

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

Until such time, if ever, as we generate significant revenue from product sales, we expect to finance our operations through the sale of equity, debt financings, marketing and distribution arrangements and collaborations, strategic alliances and licensing arrangements or other sources. We do not currently have any committed external source of funds. In addition, we may seek additional capital due to favorable market

conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the future sale of equity or convertible debt securities, including sales of our common stock pursuant to the Sales Agreement dated as of August 8, 2022 (the "Sales Agreement") with Cowen and Company, LLC ("Cowen"), each shareholder's ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect their rights as a common stockholder. In addition, debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and we may need to dedicate a substantial additional portion of any operating cash flows to the payment of principal and interest on such indebtedness. Any future indebtedness, combined with our other financial obligations, could increase our vulnerability to adverse changes in general economic, industry and market conditions, limit our flexibility in planning for, or reacting to, changes in our business and the industry and impose a competitive disadvantage compared to our competitors that have less debt or better debt servicing options. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, intellectual property, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate product candidate development or future commercialization efforts.

We have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

Rallybio was founded in January 2018 and our operations to date have been limited to financing and staffing the Company, identifying, evaluating and acquiring or in-licensing product candidates and technologies, conducting preclinical studies and our clinical trials for RLYB211, RLYB212 and RLYB116, and preclinical studies for our product candidates, and developing a pipeline of other preclinical and research programs. We have not yet demonstrated the ability to complete successfully a large-scale, pivotal clinical trial, obtain marketing approval, manufacture a commercial-scale product, or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing, obtaining marketing approval for and commercializing pharmaceutical products.

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. We will eventually need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition and, as a result, our business may be adversely affected.

Our quarterly and annual financial results may fluctuate, which makes our results difficult to predict and may cause our results to fall short of expectations.

Our financial condition and operating results have varied in the past and will continue to fluctuate from quarter-to-quarter and year-to-year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following, as well as other factors described elsewhere in this Annual Report on Form 10-K:

- variations in the level of expense related to the ongoing development of our product candidates or research pipeline;
- delays or failures in advancement of existing or future product candidates into the clinic or in clinical trials;
- the feasibility of developing, manufacturing and commercializing our product candidates;
- our relationships, and any associated exclusivity terms, with strategic collaborators;

- our execution of any additional collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements, or the termination or modification of any such existing or future arrangements;
- our operation in a net loss position in the foreseeable future;
- our ability, ourselves or with collaborators, to develop a companion diagnostic, if required, and obtain marketing approval;
- our ability to consistently manufacture our product candidates, including in sufficient quantities for clinical or commercial purposes;
- our dependence on, and the need to attract and retain, key management and other personnel;
- developments or disputes concerning patents or other proprietary rights, litigation matters and our ability to obtain and maintain patent protection for our product candidates;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- business interruptions such as power outages, strikes, civil unrest, wars, acts of terrorism or natural disasters;
- potential advantages that our competitors and potential competitors may have in developing and commercializing competing technologies or products, securing funding for or obtaining the rights to critical intellectual property;
- regulatory developments affecting our product candidates or those of our competitors; and
- our ability to use our net operating loss ("NOL") and income tax credit carryforwards to offset income tax.

Due to these and other factors, the results of any of our prior quarterly or annual periods should not be relied upon as indications of our future operating performance, and a period-to-period comparison of our results of operations may not be a meaningful indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

Our ability to use our net operating loss and income tax credit carryforwards to offset future income tax liabilities may be subject to certain limitations.

We have incurred substantial NOLs during our history. To the extent that we continue to generate taxable losses, unused losses will carry forward and can be used to offset future taxable income, if any, until such unused losses expire. NOLs generated in taxable years beginning after December 31, 2017 are not subject to expiration. Federal NOLs generated in taxable years beginning after December 31, 2017 generally may not be carried back to prior taxable years except that, under the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”), federal NOLs generated in taxable years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five taxable years preceding the taxable year in which the loss arises. Additionally, the deduction for NOLs arising in taxable years beginning after December 31, 2017 is generally limited to 80% of current year taxable income, however, as a result of the CARES Act, for taxable years beginning before January 1, 2021, the deductibility of federal NOLs generated in taxable years beginning after December 31, 2017 is not so limited. We also have substantial federal and state research and

development and other tax credit carryforwards. These 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 U.S. Internal Revenue Code of 1986, as amended, (the "Code"), a corporation that undergoes an "ownership change" is subject to limitations on its ability to use its pre-change NOLs and tax credit carryforwards to offset future taxable income. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. Some of our historical NOLs may be subject to annual limitations on our ability to use them due to prior ownership changes. Additionally, we may experience such ownership changes in the future as a result of future transactions in our stock, some of which may be outside our control. If we undergo an ownership change, our ability to use our NOLs and income tax credit carryforwards could be further limited. For these reasons, we may not be able to use a material portion of our NOLs or tax credit carryforwards, even if we attain profitability.

Risks Related to Discovery, Development, Clinical Testing, Manufacturing, and Regulatory Approval

We are heavily dependent on the success of RLYB212 and RLYB116, which are in early-stage clinical development. If we are not able to develop, obtain regulatory approval for, or successfully commercialize our product candidates, or if we experience significant delays in doing so, our business will be materially harmed.

Our lead programs are in early-stage clinical development and we do not currently have any commercial products that generate revenues or any other sources of revenue. To date, we have invested a significant portion of our efforts and financial resources in the development of RLYB212 for the prevention of FNAIT and the development of RLYB116. Our future success is substantially dependent on our ability to successfully complete preclinical and clinical development for, obtain regulatory approval for, and successfully commercialize, our product candidates, which may never occur. We currently have no products that are approved for commercial sale and may never be able to develop a marketable product. Any delays in the advancement of our clinical trials could impact our product development timelines, result in increased costs, affect our ability to obtain marketing approval according to our plans, and delay commercialization.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate the safety and efficacy of our investigational product candidates for use in each target indication through lengthy, complex and expensive preclinical studies and clinical trials. Failure can occur at any time during the preclinical study and clinical trial processes, and, because our product candidates are in an early stage of development, there is a high risk of failure, and we may never succeed in developing marketable products.

Our ability to generate product revenue will depend heavily on the successful development and eventual commercialization of our product candidates, which may never occur. Ongoing and future preclinical studies and clinical trials of our product candidates may not show sufficient safety or efficacy or be of sufficient quality to obtain or maintain regulatory approvals. There can be no assurance that any of our product candidates, even if approved, will prove to be commercially viable therapeutics.

RLYB212 and RLYB116 are designed for subcutaneous self-administration. The formulation or physical properties of RLYB212 and RLYB116 may ultimately be determined to be inadequate to support this route of administration. If subcutaneous administration is not feasible, then we may need to identify additional formulations or routes of administration, which could delay initiation of our clinical trials or commercialization and result in significant additional costs. Further, alternative formulations and routes of administration may be required to differentiate our product candidates from competitors and/or secure access to support successful commercialization.

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

- successful and timely initiation of preclinical studies, and successful and timely initiation of, enrollment in, and completion of our clinical trials with results that support a finding of safety and effectiveness and

an acceptable risk-benefit profile of our product candidates in the intended populations within the timeframes we have projected;

- regulatory grants of authorization to proceed under INDs or CTAs such that we can commence planned or future clinical trials of our product candidates;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- receipt of regulatory approvals from applicable regulatory authorities for our product candidates, and if required, in vitro diagnostic devices including companion diagnostics;
- our ability to successfully utilize certain delivery systems, such as pre-filled syringes ("PFSs"), pen-injectors and/or autoinjectors, for certain of our product candidates and to obtain regulatory approval of any such drug/device combination product;
- the outcome, timing, and cost of meeting regulatory requirements, including any post-marketing commitments, established by the FDA, EMA and other comparable foreign regulatory authorities;
- establishing commercially viable arrangements with third-party manufacturers for clinical supply and commercial manufacturing;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- establishing sales, marketing and distribution capabilities, whether alone or through a collaboration, to support commercialization of our product candidates, if and when approved;
- acceptance of the product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively differentiating and competing with other therapies approved and/or used for the same indications as our product candidates, particularly RLYB116;
- obtaining and maintaining third-party coverage and reimbursement;
- enforcing and defending intellectual property rights and claims; and
- maintaining an acceptable safety profile of the product candidates following approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to commercialize our product candidates successfully, which would materially harm our business. Due to the uncertain and time-consuming clinical development and regulatory approval process, we may not successfully develop any of our product candidates and may choose to discontinue the development of any of our product candidates. If we discontinue development of a product candidate, we will not receive anticipated revenues from that product candidate and we may not receive any return on our investment in that product candidate. We may discontinue a product candidate for clinical reasons if it does not prove to be safe and effective for its targeted indications. During clinical development, companies in our field often need to discontinue the development of product candidates if such product candidates do not achieve the necessary efficacy at tolerated doses required for patient benefit. In addition, there may be important facts about the safety, efficacy and risk versus benefit of our product candidates that are not known to us at this time. Any unexpected safety events or our failure to generate sufficient data in our clinical trials to demonstrate efficacy may cause a product candidate to fail clinical development. Furthermore, even if that product candidate meets

its safety and efficacy endpoints, we may discontinue its development for various reasons, such as changes in the competitive environment or the standard of care and the prioritization of our resources.

We may not be successful in our efforts to identify additional product candidates. Due to our limited resources and access to capital, we must prioritize development of certain product candidates, the choice of which may prove to be wrong and adversely affect our business.
We may expand our pipeline through partnering, acquiring or in-licensing additional product candidates that target validated biology. We also seek to identify and develop product candidates under our joint venture with Exscientia and our strategic alliance with AbCellera. If we fail to identify additional potential product candidates, or fail to partner, acquire or in-license additional product candidates, our business could be materially harmed.

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

- the research methodology used may not be successful in identifying potential indications or product candidates;
- potential product candidates may, after further study, be shown to have harmful or unexpected adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources than we possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through research programs, thereby limiting our ability to develop, diversify, and expand our product portfolio.

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

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects.

Preclinical studies and clinical trials are expensive, time consuming and difficult to design and implement, and involve uncertain outcomes. Any product candidates that we advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
Before obtaining marketing approval from the FDA, EMA or other comparable regulatory authorities for the sale of our product candidates, we must complete preclinical studies and extensive clinical trials to demonstrate the safety and efficacy of our product candidates. To initiate clinical trials for any future product candidates, we must submit the results of preclinical studies to the FDA, EMA or other comparable foreign regulatory authorities, along with other information, including information about CMC and our proposed clinical trial protocol, as part of an IND or similar regulatory filing that must be accepted by the FDA, EMA or other applicable regulatory authorities before we may proceed with clinical development. In the event that regulators require us to complete additional preclinical studies or we are required to satisfy other regulator requests, such as obtaining alignment on the device regulatory pathway for our FNAIT prevention program, the start of our clinical trials may be delayed or prevented. Even after we receive and incorporate guidance from these regulatory authorities, the FDA, EMA or other regulatory authorities could (i) disagree that we have satisfied their requirements to commence our clinical trial, (ii) change their position on the acceptability of our data, trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials or (iii) impose stricter requirements for approval than we currently expect.

We may experience delays in initiating and completing any clinical trials that we intend to conduct, and we do not know whether planned preclinical studies or clinical trials, will begin on time, need to be redesigned, enroll an adequate number of patients on time, or be completed on schedule, or at all. We may experience numerous unforeseen events that could delay or prevent our ability to complete current clinical trials or initiate and complete new trials, any of which may delay or prevent us from receiving marketing approval or commercializing our product candidates. These events include, but are not limited to:

- the FDA, EMA or other comparable foreign regulatory authorities requiring us to submit additional data or imposing other requirements before permitting us to commence a trial;
- delays in receiving or denial by regulatory agencies of permission to proceed with our planned clinical trials or any other clinical trials we may initiate, or placement of a clinical trial on hold;
- negative results from our non-clinical trials or clinical trials;
- challenges, delays and cost involved in identifying, recruiting and retaining suitable patients and clinical trial sites in sufficient numbers to participate in clinical trials;
- delays in reaching an agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in obtaining IRB approval at each site within the United States, or Independent Ethics Committee ("IEC") approval at sites outside the United States;
- delays or problems in analyzing data, or the need for additional analysis or data or the need to enroll additional patients;
- failure by us, our CROs, trial sites or investigators to adhere to clinical trial, regulatory, legal or contractual requirements and perform trials in accordance with the FDA's GCP requirements and trial protocol;
- inadequate quantity or quality of product candidate or other materials necessary to conduct clinical trials, for example as a result of delays in defining and implementing the manufacturing process for materials used in clinical trials or for the manufacture of larger quantities or other delays or issues arising in the manufacturing of sufficient supply of finished drug product;
- problems with designing and readiness of in vitro diagnostic devices, including companion diagnostic testing, if required, and our inability, or that of our collaborators, to develop any required laboratory diagnostic tests or companion diagnostics for RLYB212 or any other product candidate;
- lack of adequate funding to continue a clinical trial, including as a result of unanticipated costs or increases in costs of clinical trials;
- occurrence of serious adverse events including unexpected serious adverse events, associated with the product candidate or reports from non-clinical or clinical testing of our own or competing therapies that raise safety or efficacy concerns, or delays or failures in addressing patient safety concerns that arise during the course of a trial;
- changes in regulatory requirements and guidance that require changes to planned or ongoing preclinical and clinical studies, or the conduct of additional studies; and

- difficulties recruiting and retaining employees, consultants or contractors with the required level of expertise.

In addition, we could encounter delays if a clinical trial is suspended or terminated by us, the IRBs or IECs of the institutions in which such trials are being conducted, the FDA, EMA or other regulatory authorities, or recommended for termination by a Data and Safety Monitoring Board ("DSMB") for such trial. Such authorities may impose a suspension or termination or recommend an alteration to clinical trials due to several factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, the identification of safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions.

Furthermore, we rely and will rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and, while we have agreements governing their committed activities, we have limited influence over their actual performance, as described in the section titled "— Risks Related to Our Dependence on Third Parties."

Our lead product candidates, RLYB212 and RLYB116, are still in early clinical development and will require the successful completion of one or more registrational clinical trials before we are prepared to submit a BLA for regulatory approval by the FDA. We cannot predict with any certainty if or when we might complete the development of RLYB212 or RLYB116, submit a BLA for regulatory approval or whether any such BLA will be approved by the FDA.

Principal investigators for our clinical trials could serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of a clinical trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site, and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of our product candidates.

If we experience delays in the completion, or termination, of any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed or prevented. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including our focus on rare diseases.
Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timely completion of clinical trials in accordance with their protocols depends, among other things, on the speed at which we can recruit eligible patients to participate in testing our product candidates and our ability to enroll a sufficient number of patients who remain in the study until its conclusion. Clinical trial recruitment delays often result in increased costs, delays in advancing product development, delays in testing the effectiveness of technologies, delays in obtaining regulatory approval or termination of clinical trials. We may be unable to enroll a sufficient number of patients to complete any of our clinical trials, including our natural history study for our FNAIT program, and even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials.

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

- the design of the clinical trial, including the patient eligibility criteria defined in the protocol;
- the size and nature of the patient population required for analysis of the trial's primary endpoints;
- the existing body of safety and efficacy data with respect to the product candidate;
- the proximity of patients to clinical sites;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs or medical devices that may be approved for the indications we are investigating;
- competing clinical trials being conducted by other companies or institutions, particularly for RLYB116;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion; and
- other factors we may not be able to control that may limit patients, principal investigators or staff, or clinical site availability.

Additionally, we may have difficulty identifying and enrolling patients for our planned clinical trials because the conditions for which we plan to evaluate our current product candidates are rare diseases and we anticipate that there will be limited patient pools from which to draw for clinical trials. Further, because screening for many of these diseases is not widely adopted, and because it can be difficult to diagnose these diseases in the absence of screening, we may have difficulty finding patients who are eligible to participate in our studies or trials. For example, participants in clinical trials for RLYB212 have the rare HPA-1b/b genotype and we may have difficulty identifying participants for these clinical trials. In addition, our clinical trials for RLYB116 will compete with other clinical trials for product candidates that are currently being tested in clinical trials for PNH and gMG and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Furthermore, any negative results we may report in clinical trials of any of our product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials of that same or a similar product candidate.

Outside of the United States, our ability to initiate, enroll and complete a clinical trial successfully is subject to numerous additional risks, including:

- difficulty in establishing or managing relationships with CROs and physicians;
- different standards for the conduct of clinical trials;
- our inability to locate qualified local consultants, physicians and partners; and
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatment.

We may not be able to initiate or continue clinical trials required by the FDA, EMA or other regulatory authorities if we cannot enroll a sufficient number of eligible patients to participate in the clinical trials. If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials. Delays or failures in planned patient enrollment or retention may result in increased costs or program delays, which could have a harmful effect on our ability to develop our product candidates or could render further development impossible.

Results of preclinical studies, clinical trials or analyses that we may announce or publish from time to time, may not be indicative of results obtained in later trials, and any interim results we may publish could be different than final results.

The results of preclinical studies, clinical trials or analyses of the results from such trials, may not be predictive of the results of later clinical trials. Product candidates in later clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and prior clinical trials or having shown promising results based on analyses of data from earlier trials. Late-stage clinical trials may include a larger number of patients and could differ in other significant ways from early-stage clinical trials, including changes to inclusion and exclusion criteria, patient population, efficacy endpoints, dosing regimen and statistical design. Our Phase 1b clinical trial for RLYB212 was single blinded, making it difficult to predict how rapid platelet clearance will lead to prevention of alloimmunization in expectant mothers at higher risk for FNAIT and whether the results that we have observed in such trial will be repeated in larger and more advanced clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in later-stage clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding earlier promising results. In addition, conclusions based on promising data from analyses of clinical results, such as the prospective and post hoc analysis of results may be shown to be incorrect in subsequent clinical trials that have pre-specified end points or may not be considered adequate by regulatory authorities. We have completed Phase 1 clinical trials for RLYB212 and RLYB116, however, even if we complete later clinical trials as planned, we cannot be certain that their results will support the safety and efficacy requirements sufficient to obtain regulatory approval, and, as a result, our clinical development plans may be materially harmed.

In addition, interim, “top-line” and preliminary data from our clinical trials that we announce or publish may change as more patient data become available or as additional analyses are conducted. The data obtained in such clinical trials are subject to additional audit and verification procedures and following such procedures, such interim data could be materially different from the final data.

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

Adverse events or undesirable side effects caused by any product candidates we develop could cause us or regulatory authorities or IRBs, IECs or DSMBs, where applicable, to interrupt, delay, or halt clinical trials and, if we seek approval of any such product candidate, could result in a more restrictive label, imposition of a REMS program by the FDA or the delay or denial of regulatory approval by the FDA, EMA or other comparable foreign regulatory authorities. Additionally, the administration process or related procedures associated with our product candidates also may cause adverse side effects. Even if we determine that serious adverse events are unrelated to study treatment, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Results of any clinical trial we conduct could reveal a high and unacceptable severity and prevalence of side effects. For example, complement inhibitors have, by design, immunosuppressive effects and, in some cases, may be administered to patients with significantly compromised health. As a result, administration of RLYB116 could make patients more susceptible to infection. The chronic dosing of patients with RLYB116 could lead to an immune response that causes adverse reactions or impairs the activity and/or efficacy. Patients may develop an allergic reaction to the drug and/or develop antibodies directed at RLYB116, or may require immunization with a meningococcal vaccine and prophylactic antibiotics. An immune response that causes adverse reactions or impairs the activity of RLYB116 could cause a delay in or termination of our development plans.

Some potential therapeutics that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. In addition, side effects could affect patient recruitment or the ability of enrolled patients to complete a trial or result in potential clinical trial or product liability claims. Inadequate training or failures by clinical trial personnel in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Furthermore, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of subjects and limited duration of exposure, rare and severe side effects of our product candidates or those of our competitors may only be uncovered when a significantly larger number of patients have been exposed to the drug.

If we or others later identify undesirable side effects caused by any product candidate that we develop after the product is approved, several negative consequences could result, which could materially harm our business, including:

- regulatory authorities may suspend or withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings on the label, limit the approved use of such product candidate, or otherwise restrict distribution or marketing such as through requiring adoption of a REMS program;
- we may be required to conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early-stage clinical trials. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these events could prevent us from achieving or maintaining market acceptance of a product candidate, if approved, and could significantly harm our business, results of operations, and prospects.

The regulatory approval processes of the FDA, EMA and comparable foreign regulatory authorities, including the Medicines and Healthcare Products Regulatory Agency in the UK, are lengthy, time- consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for RLYB212, RLYB116 or any of our other product candidates, our business will be substantially harmed.
In the United States, we are not permitted to market a product candidate until we receive approval of a BLA or a NDA from the FDA. The process of obtaining BLA and NDA approval is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. Approval policies or regulations may change, and the FDA and other regulatory authorities have substantial discretion in the approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. In addition, the FDA may require post-approval clinical trials or studies as a condition of approval, which also may be costly. The FDA approval for a limited indication or approval with required warning language, such as a boxed warning, could significantly impact our ability to successfully market our product candidates. The FDA also may require adoption of a REMS requiring prescriber training, post-market registries, or otherwise restricting the marketing and dissemination of these products. The FDA may inform us that an approved device, including a companion diagnostic, is required to obtain marketing approval of RLYB212. Companion diagnostics are subject to regulation as medical devices and must be separately approved for marketing by the FDA. Certain of our product candidates will rely on delivery systems, such as PFSs, pen-injectors and/or autoinjectors, and may ultimately be regulated as a drug/device combination product. Although the FDA and similar foreign regulatory agencies have systems in place for the review and approval of combination products, we may experience delays in the development and commercialization of our product candidates due to regulatory timing constraints and uncertainties in the product development and approval process. Despite the time and expense invested in the clinical development of product candidates, regulatory approval is never guaranteed for our product candidates or a companion diagnostic, if required. Assuming successful clinical development, we intend to seek product approvals in countries outside the United States, including in Europe. As a result, we would be subject to regulation by the EMA, as well as the other regulatory agencies in these countries.

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

The time required to obtain approval by the FDA, EMA and other comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that we will never obtain regulatory approval for any product candidate.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we must demonstrate to the satisfaction of the FDA, EMA or other comparable foreign regulatory authority, that such product candidates are safe and effective for their intended uses. Data obtained from preclinical studies and clinical trials are susceptible to varying interpretations, and regulatory authorities may not interpret our data as favorably as we do, which may further delay, limit, or prevent development efforts, clinical trials, or marketing approval. Even if we believe the preclinical or clinical data for our product candidates are sufficient to support approval, such data may not be considered sufficient to support approval by the FDA, EMA and other comparable regulatory authorities.

For example, we have proposed to use real-world data from our FNAIT natural history study to support our development program and related regulatory submissions for RLYB212. Specifically, the natural history study data would assist us in assessing the frequency of women at higher risk of FNAIT among women of different racial and ethnic characteristics and the occurrence of HPA-1a alloimmunization in these women. The natural history studies and other real-world evidence we may submit to support applications for marketing approval may not be accepted by the FDA, EMA, or other comparable foreign regulatory authorities.

The FDA, EMA or other comparable foreign regulatory authority can delay, limit, or deny approval of RLYB212, RLYB116 or any of our other product candidates that we develop or require us to conduct additional preclinical or clinical testing or abandon a program for many reasons, including, but not limited to:

- the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, EMA or other comparable foreign regulatory authorities that our product candidate is safe and effective for its proposed indication;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates, or other products containing an active ingredient in our product candidates;
- negative or ambiguous results from our clinical trials or results that may not meet the level of statistical significance required by the FDA, EMA or other comparable foreign regulatory authorities for approval;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety and efficacy in the full population for which we seek approval;
- the FDA, EMA or other comparable foreign regulatory authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States or the applicable foreign jurisdiction;
- we may be unable to demonstrate that our product candidate's clinical and other benefits outweigh its safety risks;
- the FDA, EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

- the data collected from clinical trials of our product candidates may not be acceptable or sufficient to support the submission of a BLA or NDA or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical trials;
- the FDA's or the applicable foreign regulatory authority's disagreement regarding the formulation, the labeling, and/or the specifications of our product candidates;
- the FDA, EMA, or other comparable foreign regulatory authorities may require us to obtain clearance or approval of a companion diagnostic test;
- additional time may be required to obtain regulatory approval for our product candidates because they are combination products;
- the FDA, EMA or other comparable foreign regulatory authorities may fail to approve or find deficiencies with the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

We have never obtained marketing approval for a product candidate. It is possible that the FDA may refuse to accept for substantive review any BLAs or NDAs that we submit for our product candidates or may conclude after review of our data that our applications are insufficient to obtain marketing approval of our product candidates. If the FDA does not accept or approve our BLAs or NDAs for our product candidates, it may require that we conduct additional clinical, preclinical, or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any BLA or NDA that we submit may be delayed or prevented, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our BLA or NDA. Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing our product candidates, generating revenues, and achieving and sustaining profitability.

Our product candidates target rare diseases and conditions, and the market opportunities for RLYB212, RLYB116 or any of our other product candidates, if approved, may be smaller than we anticipate. As a result, our commercial opportunity may be limited and because the target populations of our product candidates are for rare diseases, we must be able to successfully identify patients and capture a significant market share to achieve profitability and growth.

Our product candidates target rare diseases and conditions. We are developing RLYB212 for the potential prevention of FNAIT, and we estimate that each year greater than 22,000 pregnancies are at high risk for FNAIT in the United States, Canada, the UK, other major European countries and Australia, based on the presence of HLA DRB3*01:01 positive and HPA-1a negative antibody in mothers and HPA-1a positive in the fetus. With respect to RLYB116, we estimate that there are approximately 4,700 patients with PNH and up to 60,000 patients with gMG in the United States. Our projections of the number of eligible patients are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, population statistics and market research, and may prove to be incorrect. Further, new sources may reveal a change in the estimated number of eligible patients, and the number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our current programs or future product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to. For example, even if we obtain FDA approval for RLYB212 or RLYB116, the drug may be approved for a target population that is more limited than what we currently anticipate. Furthermore, even if we obtain significant market share for any product candidate, if approved, the potential target populations for our product candidates are for rare diseases, and we may never achieve profitability.

Further, in many cases there are either no or limited screening or diagnostic tests for the indications our product candidates are being developed to potentially treat. For example, the successful prevention of FNAIT in mothers at risk for developing this rare disorder will require identifying expectant mothers who are HPA-1 negative and HLA-DRB3*01:01 positive and HPA-1a positive in the fetus. In collaboration with partners, we may develop screening and diagnostics tests to help us to identify individuals at risk, and the FDA, EMA or other comparable foreign regulatory authorities may require us to do so. The lack of screening and diagnostic tests, coupled with the fact that there is frequently limited awareness among certain health care providers concerning the rare diseases we may seek to treat, often means that a proper diagnosis can, and frequently does, take years to identify (or an appropriate diagnosis may never be made for certain patients). As a result, even if one of our product candidates is approved for commercial sale, we may not be able to grow our revenues due to difficulty in identifying eligible patients. There can be no guarantee that any of our programs will be effective at identifying patients that will benefit from our product candidates, and even if we can identify patients that our product candidates can help, the number of patients that our product candidates may ultimately treat may turn out to be lower than we expect, they may not be otherwise amenable to treatment with our product candidates, or new patients may become increasingly difficult to identify, all of which may adversely affect our ability to grow and generate revenue and adversely affect our results of operations and our business. In addition, even in instances where we are able to expand the number of patients being treated, the number may be offset by the number of patients that discontinue use of the applicable product in a given period resulting in a net loss of patients and potentially decreased revenue.

The FDA, EMA or other comparable foreign regulatory authorities, including the MHRA, could require the clearance or approval of an in vitro diagnostic or companion diagnostic device as a condition of approval for any product candidate that requires or would commercially benefit from such tests, including RLYB212. Failure to successfully validate, develop and obtain regulatory clearance or approval for companion diagnostics on a timely basis or at all could harm our drug development strategy and we may not realize the commercial potential of any such product candidate.

If safe and effective use of RLYB212 or any of our other product candidates depends on an in vitro diagnostic, then the FDA generally will require approval or clearance of that test, known as a companion diagnostic, at the same time that the FDA approves our product candidates. The process of development and approval of such diagnostic is time consuming and costly. Companion diagnostics, which provide information that is essential for the safe and effective use of a corresponding therapeutic product, are subject to regulation by the FDA, EMA and other comparable foreign regulatory authorities as medical devices and require separate regulatory approval from therapeutic approval prior to commercialization. The FDA previously has required in vitro diagnostic tests intended to select the patients who will respond to a product candidate to obtain a PMA simultaneously with approval of the therapeutic candidate. The PMA process, including the gathering of preclinical and clinical data and the submission and review by the FDA, can take several years or longer. It involves a rigorous pre-market review during which the applicant must prepare and provide FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing, and labeling. After a device is placed on the market, it remains subject to significant regulatory requirements, including requirements governing development, testing, manufacturing, distribution, marketing, promotion, labeling, import, export, record-keeping, and adverse event reporting.

Given our limited experience in developing and commercializing in vitro diagnostic devices, including companion diagnostic tests, we do not plan to develop such tests internally and thus will be dependent on the sustained cooperation and effort of third-party collaborators in developing and obtaining approval for these in vitro diagnostic tests. We may not be able to enter into arrangements with a provider to develop screening and/or diagnostic tests for use in connection with a registrational trial for RLYB212 or for commercialization of RLYB212, or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of RLYB212. We and our future collaborators may encounter difficulties in developing and obtaining approval for such tests, including issues relating to selectivity/specificity, analytical validation, reproducibility, or clinical validation. Any delay or failure by our collaborators to develop or obtain regulatory approval of in vitro diagnostic tests could delay or prevent approval of RLYB212 or any of our other product candidates. In addition, we, our collaborators or third parties may encounter production difficulties that could constrain the supply of such tests, and both they and we may have difficulties gaining acceptance of the use of such tests by physicians. We believe that adoption of screening and treatment into clinical practice guidelines is important for market access, third-party payer reimbursement, utilization in medical practice and commercial success. Both our collaborators and we may have difficulty gaining acceptance of such screening

and/or diagnostic tests into clinical practice guidelines. If such tests fail to gain market acceptance, it would have an adverse effect on our ability to derive revenues from sales, if any, of RLYB212 if it is approved for commercial sale, or any other approved products that require an in vitro diagnostic test. In addition, any collaborator or third-party with whom we contract may decide not to commercialize or to discontinue selling or manufacturing the test that we anticipate using in connection with development and commercialization of our product candidates, or our relationship with such collaborator or third-party may otherwise terminate. We may not be able to enter into arrangements with another provider to obtain supplies of an alternative in vitro diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

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

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to acquire, develop, and obtain marketing approval for new products on a cost-effective basis and to market them successfully. If a product candidate we develop is approved, we will face intense competition. There are many public and private biopharmaceutical companies, universities, government agencies and other research organizations actively engaged in the research and development of products that may be like our product candidates or address similar markets. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. In addition, the number of companies seeking to develop and commercialize products and therapies competing with our product candidates is likely to increase. However, we seek to build our portfolio with key differentiating attributes to provide a competitive advantage in the markets we target. We believe RLYB212 could be a first-in-class antibody for the prevention of FNAIT, and no direct mechanistic based clinical competition currently exists. Our second product candidate, RLYB116 faces competition from a number of companies for the treatment of patients with PNH and gMG, including Soliris and Ultomiris marketed by AstraZeneca. If we successfully develop and, if approved, commercialize RLYB116, this therapy may compete, or potentially be used in conjunction, with currently marketed treatments, including Soliris and Ultomiris, and any new therapies that may become available in the future.

Competition could render any product candidate we develop obsolete, less competitive, or uneconomical. In addition, product candidates developed by our competitors may prove to be more safe or more effective than our product candidates. Our competitors may, among other things:

- have significantly greater name recognition and financial, manufacturing, marketing, product development, technical, commercial infrastructure, and human resources than we do;
- more effectively recruit and retain qualified scientific and management personnel;
- more effectively establish clinical trial sites and patient registration;
- develop and commercialize products that are safer, more effective, less expensive, more convenient, or easier to administer, or have fewer or less severe side effects;
- obtain quicker regulatory approval;
- better protect their patents and intellectual property or acquire technologies that are complementary to, or necessary for, our programs;
- implement more effective approaches to sales, marketing, pricing, coverage, market access, and reimbursement; or

- form more advantageous strategic alliances or collaborations.

If we are not able to effectively compete for any of the foregoing reasons, our business will be materially harmed.

Disruptions in the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.
The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, 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.

Even if we obtain FDA approval for a product candidate in the United States, we or our current or future collaborators may never obtain approval for or commercialize the product candidate in any other jurisdiction, which would limit our ability to realize its full market potential.
In order to market any product in a particular jurisdiction, we or our current or future collaborators must establish and comply with numerous and varying regulatory requirements regarding safety and efficacy on a country-by-country basis. Approval by the FDA in the United States does not ensure approval by comparable regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our or our collaborators' ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time- consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we or our collaborators fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and we will be unable to realize the full market potential of any product we develop.

Even if we obtain regulatory approval for any of our product candidates, we will still face extensive and ongoing regulatory requirements and obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with any product candidates.
Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval preclinical and clinical testing, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, and advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of the FDA and other regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, establishment registration and drug listing requirements, continued compliance with cGMP requirements regarding the distribution of samples to physicians and recordkeeping and GLP and GCP requirements for non-clinical studies and any clinical trials that we conduct post-approval.

The FDA may also require costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. Additionally, the FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in a manner that is consistent with the provisions of the approved labeling. If we market our products for uses beyond their approved indications or otherwise inconsistent with the FDA-approved labeling, we may be subject to enforcement action for off-label marketing by the FDA and other federal and state enforcement agencies, including the Department of Justice. Violation of the FDCA and other statutes, including the False Claims Act, and equivalent legislation in other countries relating to the promotion and advertising of prescription products may also lead to investigations or allegations of violations of federal and state and other countries' health care fraud and abuse laws and state consumer protection laws. Even if it is later determined we were not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our actions and have to divert significant management resources from other matters.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers, or manufacturing processes or failure to comply with regulatory requirements, may yield various results, including, but not limited to:

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

If we obtain FDA approval for RLYB212 or RLYB116, safety risks not identified in our prior clinical trials may first appear after we obtain approval and commercialize these product candidates. Any new post-marketing adverse events may significantly impact our ability to market the drugs and may require that we recall and discontinue commercialization of the products. Furthermore, if any confirmatory post-marketing trial fails to confirm the clinical profile or clinical benefits of RLYB212 or RLYB116, the FDA may withdraw its approval, which would materially harm our business.

We also cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. Further, the FDA's, EMA's and other comparable regulatory authorities' policies may change, and additional government regulations may

be enacted that could prevent, limit, or delay regulatory approval of a product candidate or increase the costs and regulatory burden of commercialization. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition, and results of operations. Furthermore, non-compliance by us or any collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, may also result in significant financial penalties, which would adversely affect our business.

We may seek Fast Track designation, Breakthrough Therapy designation, or the PRIME designation for our product candidates, but we might not receive any such designation, and even if we do, such designation may not actually lead to a faster development or regulatory review or approval process.

If a drug is intended for the treatment of a serious or life-threatening condition, and non-clinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product candidate may qualify for FDA Fast Track designation, for which sponsors must apply. Sponsors of fast-track products may have more frequent interactions with the FDA, and, in some circumstances, the FDA may initiate review of sections of a fast track product's application before the application is complete. We may submit an application for Fast Track designation for RLYB212 and RLYB116. The FDA has broad discretion whether to grant this designation, and we may not receive it. Moreover, even if we receive Fast Track designation, Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular time frame. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

We also may seek a Breakthrough Therapy designation for RLYB212 or other product candidates if future results support such designation. A Breakthrough Therapy is defined as a drug (including biologic) that is intended, alone or in combination with one or more other drugs, to treat a serious condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Sponsors of products that have been designated as breakthrough therapies are eligible to receive more intensive FDA guidance on establishing an efficient drug development program, an organization commitment involving senior managers, and may be eligible for rolling review. Drugs designated as breakthrough therapies by the FDA may also be eligible for other expedited review programs, including accelerated approval and priority review, if supported by clinical data at the time the BLA or NDA is submitted to the FDA.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe that RLYB212 meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. Even if we receive Breakthrough Therapy designation, the receipt of such designation may not result in a faster development or regulatory review or approval process compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if RLYB212 qualifies as a Breakthrough Therapy, the FDA may later decide that RLYB212 no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

In the European Union ("EU") we may seek PRIME designation for some of our product candidates in the future. PRIME is a voluntary program aimed at enhancing the EMA's role to reinforce scientific and regulatory support in order to optimize development and enable accelerated assessment of new medicines that are of major public health interest with the potential to address unmet medical needs. The program focuses on medicines that target conditions for which there exists no satisfactory method of treatment in the EU or even if such a method exists, it may offer a major therapeutic advantage over existing treatments. PRIME is limited to medicines under development and not authorized in the EU and the applicant intends to apply for an initial marketing authorization application through the centralized procedure. To be accepted for PRIME, a product candidate must meet the eligibility criteria in respect of its major public health interest and therapeutic innovation based on information that can substantiate the claims. The benefits of a PRIME designation include the appointment of a Committee for Medicinal Products for Human Use rapporteur to provide continued support and

help to build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME enables an applicant to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if we receive PRIME designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of EMA's grant of a marketing authorization.

We may be unsuccessful in obtaining or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity. If our competitors are able to obtain orphan drug exclusivity for products that constitute the same drug and treat the same indications as RLYB212 and RLYB116 or any of our other product candidates, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.

Regulatory authorities in some jurisdictions, including the United States and the EU may designate drugs for relatively small patient populations as orphan drugs. Under the U.S. Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population of more than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the EU, the EMA's Committee for Orphan Medicinal Products evaluates, and the European Commission grants, an orphan drug designation principally to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the EU. In addition, the product under consideration is indicated for a condition where there exists no satisfactory method of diagnosis, prevention or treatment authorized in the EU or, if such method exists, that the medicinal product will be of significant benefit to those affected by that condition. Each of the FDA and the European Commission has granted orphan drug designation for RLYB212 for the treatment of FNAIT. We may seek orphan drug designation in the United States and the EU for our other product candidates but may be unsuccessful in doing so. There can be no assurance that the FDA or the EMA's Committee for Orphan Medicinal Products will consider orphan designation for any indication for which we apply or re-apply, or that we will be able to maintain such designation. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

If a product candidate with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug or biologic for the same orphan designation for that time period, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity. In the United States, the exclusivity period is seven years. The applicable exclusivity period is ten years in Europe, but such exclusivity period can be reduced to six years in Europe if a product no longer meets the criteria for orphan designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Similarly, in the EU, the market exclusivity can be broken if the holder of the marketing authorization for the original orphan medicinal product is unable to supply sufficient quantities of the medicinal product. In addition, in both the United States and EU, if a different drug is subsequently approved for marketing for the same or a similar indication as any of our product candidates that receive marketing approval, we may face increased competition and lose market share regardless of orphan drug exclusivity, which only protects against approval of the "same" drug for the same indication.

We may seek accelerated approval by the FDA for one or more of our product candidates. Accelerated approval by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may in the future seek an accelerated approval for our one or more of our product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. As a condition of approval, the FDA requires that a sponsor of a product receiving accelerated approval perform a post-marketing confirmatory clinical trial or trials. In addition, the FDA currently requires as a condition for accelerated approval the pre-submission of promotional materials to FDA for review.

Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a BLA for accelerated approval or any other form of expedited development, review or approval. Furthermore, if we decide to submit an application for accelerated approval there can be no assurance that such submission or application will be accepted or that the FDA will determine that the product candidate is eligible for or grant accelerated approval. A failure to obtain any planned accelerated approval for our product candidates would result in a longer time period to commercialization of our product candidates, if approved, could increase the cost of development of our product candidates and could harm our competitive position in the marketplace. If we receive accelerated approval for any of our product candidates, the FDA may withdraw accelerated approval if, among other things, a confirmatory trial required to verify the predicted clinical benefit of the product fails to verify such benefit or if such trial is not conducted with due diligence. Withdrawal of any accelerated approval could substantially harm our business.

Although RLYB212 has received FDA designation as rare pediatric disease drug products, any marketing application we submit for RLYB212 may not qualify for issuance of a rare pediatric disease priority review voucher.
In the United States, RLYB211 and RLYB212 have received designation from the FDA as rare pediatric disease drug products. Receipt of rare pediatric disease designation is a prerequisite to qualifying for receipt of a rare pediatric disease priority review voucher upon approval of a marketing application for the rare pediatric disease drug product. The priority review voucher may be used to obtain priority review of a future marketing application that would not otherwise qualify to receive priority review. Priority review shortens the FDA's goal for taking action on a marketing application from ten months to six months for an original BLA or NDA from the date of filing. As an alternative to using the priority review voucher to obtain priority review of one of its own marketing applications, the sponsor of a rare pediatric disease drug product receiving a priority review voucher may also sell or otherwise transfer the voucher to another company. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted an application relying on the priority review voucher. The FDA may also revoke any rare pediatric disease priority review voucher if the rare pediatric disease product for which the voucher was awarded is not marketed in the United States within one year following the date of approval.

There is no guarantee that, if we ever submit and obtain approval for RLYB212 or any other product candidate for which we may obtain rare pediatric disease designation in the future, we will receive a rare pediatric disease priority review voucher. In addition to receiving rare pediatric disease designation, in order to receive a rare pediatric disease priority review voucher, the NDA or BLA must be granted priority review, rely on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population, not seek approval for a different adult indication in the original rare pediatric disease product application and be for a drug that does not include a previously approved active ingredient. Under current statutory sunset provisions, even if a marketing application meets all of these requirements, the FDA may only award a voucher prior to September 30, 2026 and only if the approved product received rare pediatric disease drug product designation prior to September 30, 2024. We cannot be certain that we will receive approval for any of our rare pediatric disease designated products prior to the statutory sunset date, if ever. Moreover, even if we believe that our marketing application meets the other requirements to be eligible to receive a priority review voucher upon approval, the FDA may disagree.

The successful commercialization of any product candidate we develop will depend in part on the extent to which regulatory authorities and private health insurers establish coverage and reimbursement. Failure to obtain or maintain coverage and reimbursement for our product candidates,

if approved, could limit our or our collaborators' ability to market those products and decrease our or our collaborators' ability to generate revenue.

If any product candidate is approved for marketing, coverage and reimbursement for any such product by governmental healthcare programs, such as Medicare and Medicaid, private health insurers, and other third-party payors would be essential for most patients to be able to afford the prescription medication. Our ability to achieve acceptable levels of coverage and reimbursement for products or procedures using our products by regulatory authorities, private health insurers and other third-party payors will therefore have an effect on our ability to successfully commercialize any product candidates we develop. We cannot be sure that coverage and reimbursement will be available for our product candidates, if and when such candidates obtain marketing approval, and any reimbursement that may become available may not be adequate and may be decreased or eliminated in the future.

Moreover, increasing efforts by governmental and third-party payors in the United States to cap or reduce healthcare costs may cause third-party payors to limit both coverage and the level of reimbursement for newly approved products and, as a result, such payors may not cover or provide adequate payment for any product we commercialize. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care and additional legislative, administrative, or regulatory changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and related administration procedures, has become intense and new products face increasing challenges in entering the market successfully. Third-party payors are increasingly challenging the price and examining the cost-effectiveness of new products in addition to their safety and efficacy. To obtain or maintain coverage and reimbursement for any current or future product, we may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our product. These studies will be in addition to the studies required to obtain regulatory approvals.

We may also need to provide discounts to purchasers to encourage purchasing of any approved product and rebates to third party payors to increase the possibility of favorable coverage and adequate cost sharing thresholds for patients. We may be required to provide discounts or rebates on any approved product under government healthcare programs or to certain government and private purchasers in order to obtain coverage under federal health care programs such as Medicaid. Participation in such programs would require us to track and report certain drug prices. We may be subject to fines and other penalties if we fail to report such prices accurately.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor, and one third-party payor's decision to cover a particular product does not ensure that other payors will also provide similar coverage. Additionally, the process for determining whether a third-party payor will provide coverage for a product is typically separate from the process for setting the price of such product or establishing the reimbursement rate that the payor will pay for the product once coverage is approved. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and reimbursement will be obtained or will be consistent across payors. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely. If coverage or reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on our product candidates.

We or our collaborators may also be subject to extensive governmental price controls and other market regulations outside of the United States, and we believe the increasing emphasis on cost-containment initiatives in other countries have and will continue to put pressure on the pricing and usage of medical products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we or our collaborators are able to charge for products we or our collaborators commercialize. Accordingly, in markets outside of the United States, the reimbursement for products we or our collaborators commercialize may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

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

Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Commercial success also will depend, in large part, on the coverage and reimbursement of our product candidates and associated screening and/or diagnostic tests by third-party payors, including private insurance providers and government payors. Various factors will influence whether our product candidates are accepted in the market if approved for commercial sale, including, but not limited to:

- the efficacy, safety and tolerability of our products, and potential advantages compared to alternative treatments;
- the clinical indications for which the product is approved, and product labeling or product insert requirements of the FDA, EMA or other comparable foreign regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- the effectiveness of sales and marketing efforts;
- the prevalence and severity of any side effects;
- the cost of treatment in relation to alternative treatments, including any similar treatments;
- our ability to offer our products for sale at competitive prices;
- the availability and access to screening and/or diagnostic tests;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and reimbursement for any of our products that are approved and any screening and/or diagnostic testing, as appropriate; and
- any restrictions on the use of our product together with other medications.

Market acceptance of our product candidates is heavily dependent on patients' and physicians' perceptions that our product candidates are safe and effective treatments for their targeted indications and willingness to use screening and/or diagnostic tests to identify at-risk target populations for our therapeutics. The perceptions of any product are also influenced by perceptions of competitors' products that are in the same class or that have a similar mechanism of action. Because we expect sales of our product candidates, if approved, to generate substantially all our revenues in the foreseeable future, the failure of our product candidates to find market acceptance would harm our business and could require us to seek additional financing.

If approved, our product candidates that are regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway.

The BPCIA was enacted as part of the Patient Protection and Affordable Care Act (the "ACA") to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the

reference biological product until four years after the date of first licensure of the reference product. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still develop and receive approval of a competing biologic, so long as their BLA does not rely on the reference product, sponsor's data or submit the application as a biosimilar application. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty, and any new policies or processes adopted by the FDA could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of the product candidates we develop that is approved in the United States as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. The approval of a biosimilar of our product candidates could have a material adverse impact on our business due to increased competition and pricing pressure.

If the FDA, EMA or other comparable foreign regulatory authorities approve generic versions of any of our small molecule investigational products that receive marketing approval, or such authorities do not grant our products appropriate periods of exclusivity before approving generic versions of those products, the sales of our products, if approved, could be adversely affected.

Once an NDA is approved, the product covered thereby becomes a "reference listed drug" in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the Orange Book. Manufacturers may seek approval of generic versions of reference listed drugs through submission of ANDAs in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical trials to assess safety and efficacy. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labelling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug is typically lost to the generic product.

The FDA may not approve an ANDA for a generic product until any applicable period of non-patent exclusivity for the reference listed drug has expired. The FDCA provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity. Specifically, in cases where such exclusivity has been granted, an ANDA may not be submitted to the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification that a patent covering the reference listed drug is either invalid or will not be infringed by the generic product, in which case the applicant may submit its application four years following approval of the reference listed drug.

Generic drug manufacturers may seek to launch generic products following the expiration of any applicable exclusivity period we obtain if our products are approved, even if we still have patent protection for such products. Competition that our products could face from generic versions of our products could materially and adversely affect our future revenue, profitability, and cash flows and substantially limit our ability to obtain a return on the investments we have made in those product candidates.

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

In order to market and successfully commercialize any product candidates we develop, if approved, we must build our sales and marketing capabilities or enter into collaborations with third parties for these services. We currently have no sales, marketing or distribution capabilities and as a company have no experience in marketing products. If we commercialize any of our product candidates that may be approved ourselves, we will need to develop an in-house marketing organization and sales force across rare disease therapeutic areas, which will require significant expenditures, management resources, and time. There are significant expenses

and risks involved with establishing our own sales and marketing capabilities, including our ability to hire, train, retain, and appropriately incentivize a sufficient number of qualified individuals, generate sufficient sales leads and provide our sales and marketing team with adequate access to physicians who may prescribe our products, effectively manage a geographically dispersed sales and marketing team, and other unforeseen costs and expenses. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, and retrain marketing and sales personnel. Any failure or delay in the development of a product candidate that affects the expected timing of commercialization of the product candidate or results in the failure of the product candidate to be commercialized could result in us having prematurely or unnecessarily incurred costly commercialization expenses. Our investment would be lost if we are unable to retain or reposition our sales and marketing personnel.

We may also enter into collaborations for the sales and marketing of our product candidates, if approved. To the extent that we depend on collaborators for sales and marketing activities, any revenues we receive will depend upon the success of those collaborators' sales and marketing teams and the collaborators' prioritization of our products and compliance with applicable regulatory requirements, and there can be no assurance that the collaborators' efforts will be successful. If we are unable to build our own sales and marketing team or enter into a collaboration for the commercialization of product candidates we develop, if approved, we may be forced to delay the commercialization of our product candidates or reduce the scope of our sales or marketing activities, which would have an adverse effect on our business, operating results and prospects.

Risks Related to Our Dependence on Third Parties

We intend to continue to pursue business development transactions focused on the in-license of additional product candidates or the out-license of rights to product candidates in our pipeline and collaborate with third parties for the development and commercialization of our product candidates. We may not succeed in identifying and acquiring businesses or assets, in-licensing intellectual property rights or establishing and maintaining collaborations, which may significantly limit our ability to successfully develop and commercialize our other product candidates, if at all, and these transactions could disrupt our business, cause dilution to our stockholders or reduce our financial resources.

We acquired all rights to RLYB212 from Prophylix in 2019 and rights to RLYB116 and RLYB114 from Sobi in 2019. We also obtained worldwide exclusive rights to Sanofi's KY1066, now referred to as RLYB331, and have entered into a joint venture with Exscientia for the development of small molecule therapeutics for rare diseases, a discovery and collaboration agreement with AbCellera to discover, develop, and commercialize novel antibody-based therapeutics for rare diseases, and a research collaboration with EyePoint to explore and assess the viability of utilizing our inhibitor of C5 in EyePoint's proprietary technology for sustained intraocular delivery. An important component of our approach to product development is to acquire or in-license rights to product candidates, products or technologies, acquire other businesses or enter into collaborations with third parties. We may not be able to enter into such transactions on favorable terms, or at all. Any such acquisitions, in-licenses or collaborations may not strengthen our competitive position, and these transactions may be viewed negatively by analysts, investors, customers, or other third parties with whom we have relationships. We may decide to incur debt in connection with an acquisition, or in-license or issue our common stock or other equity securities as consideration for the acquisition, which would reduce the percentage ownership of our existing stockholders.

We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the sellers of the acquired business. In addition, we may not be able to successfully integrate the acquired personnel, technologies, and operations into our existing business in an effective, timely, and non-disruptive manner. Such transactions may also divert management attention from day-to-day responsibilities, increase our expenses, and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or in-licenses or the effect that any such transactions might have on our operating results.

We may not realize the anticipated benefits of any current or future collaboration, each of which involves or will involve numerous risks, including:

- a collaborator may shift its priorities and resources away from our product candidates due to a change in business strategies, or a merger, acquisition, sale, or downsizing;

- a collaborator may seek to renegotiate or terminate its relationships with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- a collaborator may cease development in therapeutic areas that are the subject of our collaboration;
- a collaborator may not devote sufficient capital or resources towards our product candidates, or may fail to comply with applicable regulatory requirements;
- a collaborator may change the success criteria for a product candidate, thereby delaying or ceasing development of such candidate;
- a significant delay in initiation of certain development activities by a collaborator will also delay payment of milestones tied to such activities, thereby impacting our ability to fund our own activities;
- a collaborator could develop a product that competes, either directly or indirectly, with our product candidates;
- a collaborator with commercialization obligations may not commit sufficient financial resources or personnel to the marketing, distribution, or sale of a product;
- a collaborator with manufacturing responsibilities may encounter regulatory, resource, or quality issues and be unable to meet demand requirements;
- a collaborator may terminate a strategic alliance;
- a dispute may arise between us and a collaborator concerning the research, development, or commercialization of a product candidate resulting in a delay in milestones or royalty payments or termination of the relationship and possibly resulting in costly litigation or arbitration, which may divert management's attention and resources; and
- a collaborator may use our products or technology in such a way as to invite litigation from a third-party.

If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development, manufacturing, or commercialization efforts related to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. If we are unable to establish and maintain collaborations on acceptable terms or to successfully transition away from terminated collaborations, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense, or find alternative sources of capital, which would have a material adverse impact on our clinical development plans and business. If we fail to establish and maintain collaborations related to our product candidates, we could bear all of the risk and costs related to the development of any such product candidate, and we may need to seek additional financing, hire additional employees and otherwise develop expertise for which we have not budgeted. This could negatively affect the development and commercialization of our product candidates.

We may face significant competition in identifying and acquiring businesses or assets, in-licensing intellectual property rights and seeking appropriate collaboration partners for our product candidates, and the negotiation process may be time-consuming and complex. In order for us to successfully partner our product candidates, potential collaborators must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other products or product candidates available for licensing from or in connection with collaborations with other companies. Our success in acquiring business or assets or in partnering with collaborators may depend on our history or perceived capability of successful product development. Even if we are successful in our efforts to acquire businesses or assets, in-license

intellectual property rights or establish collaborations, we may not be successful in developing such products candidates or technologies or able to maintain such collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing.

Our reliance on a central team consisting of a limited number of employees and third parties who provide various administrative, research and development, and other services across our organization presents operational challenges that may adversely affect our business. As of December 31, 2023, we had 43 full-time employees, upon whom we rely for various administrative, research and development, business development and other support services shared among our subsidiaries and the Exscientia joint venture. The size of our centralized team may limit our ability to devote adequate personnel, time, and resources to support the operations of all of our subsidiaries and the Exscientia joint venture, including their research and development activities, the management of financial, accounting, and reporting matters, and the oversight of our third-party vendors and partners. If our centralized team or our third-party vendors and partners performing such functions fail to provide adequate administrative, research and development, or other services across our entire organization, our business, financial condition, and results of operations could be harmed.

Our employees and independent contractors, including principal investigators, CROs, consultants, vendors, and any third parties we may engage in connection with development and commercialization may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business. Misconduct by our employees and independent contractors, including principal investigators, CROs, consultants, vendors and any third parties we may engage in connection with research, development, regulatory, manufacturing, quality assurance and other pharmaceutical functions and commercialization, could include intentional, reckless or negligent conduct or unauthorized activities that violate: (i) the laws and regulations of the FDA, and other similar regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) data privacy, security, fraud and abuse and other healthcare laws and regulations; or (iv) laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Activities subject to these or other laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government agency could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us or them and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal, and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

We currently rely and will rely on third parties for the manufacture of drug substance for our preclinical studies and clinical trials and expect to continue to do so for commercialization of any product candidates that we may develop that are approved for marketing. We also rely and will rely on third parties for the design and manufacture of companion diagnostics related to RLYB212 and any other product candidates that may require a companion diagnostic. Our reliance on third parties may increase the risk that we will not have sufficient quantities of such drug substance, product candidates, or any products that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.

We have limited personnel with experience in manufacturing, and we do not own facilities for manufacturing RLYB212 and RLYB116 or any other product candidate. Instead, we rely on and expect to continue to rely on contract manufacturers for the supply of cGMP-drug substance and drug product of RLYB212 and RLYB116 and any other product candidates we develop and, in the future, for commercial supply. Reliance on third parties may expose us to more risk than if we were to manufacture our product candidates ourselves.

We may be unable to establish necessary supply agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the possible breach of the manufacturing agreement by the third-party;
- the possible termination or nonrenewal of the agreement by the third-party at a time that is costly or inconvenient for us;
- reliance on the third-party for regulatory compliance, quality assurance, safety, and pharmacovigilance and related reporting; and
- the possible inability of third-party suppliers to supply and/or transport materials, components and products to us in a timely manner as a result of disruptions to the global supply chain.

Third-party manufacturers may fail to comply with cGMP regulations or similar regulatory requirements outside the United States. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of our product candidates for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Moreover, our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or medicines, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our medicines and harm our business, financial condition, results of operations, and prospects.

While we provide oversight of manufacturing activities, we have limited ability to control the execution of manufacturing activities by, and are or will be dependent on, our CMOs for compliance with cGMP requirements for the manufacture of our product candidates by our CMOs. As a result, we are subject to the risk that our product candidates may have manufacturing defects or fail to comply with regulatory requirements, which we have limited ability to prevent. CMOs may also have competing obligations that prevent them from manufacturing our product candidates in a timely manner. If a CMO cannot successfully manufacture drug substance that conforms to our specifications and the regulatory requirements, we will not be able to secure or maintain regulatory approval for the use of our product candidates in clinical trials, or for commercial distribution of our product candidates, if approved. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance, and qualified personnel, and we were not involved in developing our CMOs' policies and procedures.

The facilities and processes used to manufacture our product candidates are subject to inspection by the FDA, EMA and other comparable foreign authorities. If the FDA, EMA or other comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval or finds deficiencies in the future, we may need to find alternative manufacturing facilities or conduct additional studies, which would delay our development program and significantly impact our ability to develop, obtain regulatory approval for, or commercialize our product candidates, if approved. Furthermore, CMOs may breach existing agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreement at a time that is costly or otherwise inconvenient for us. Finding new CMOs or third-party suppliers involves additional cost and requires our management's time and focus. In addition, there is typically a transition period when a new CMO commences work.

Any significant delay in the supply of our product candidates or the raw materials needed to produce our product candidates, could considerably delay conducting our clinical trials and potential regulatory approval of our product candidates. If we were unable to find an adequate CMO or another acceptable solution in time, our clinical trials could be delayed, or our commercial activities could be harmed.

We rely on and will continue to rely on CMOs to purchase from third-party suppliers the raw materials necessary to produce our product candidates. We have limited ability to control the process or timing of the acquisition of these raw materials by our CMOs. Moreover, we currently do not have any agreements for the production of these raw materials. Supplies of raw materials could be interrupted from time to time and we cannot be certain that alternative supplies could be obtained within a reasonable time frame, at an acceptable cost, or at all. In addition, a disruption in the supply of raw materials could delay the commercial launch of our product candidates, if approved, or result in a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates. Growth in the costs and expenses of raw materials may also impair our ability to cost effectively manufacture our product candidates. There are a limited number of suppliers for the raw materials that we may use to manufacture our product candidates and we may need to assess alternative suppliers to prevent a possible disruption of the manufacture of our product candidates. Moreover, our product candidates utilize drug substances that are produced on a small scale, which could limit our ability to reach agreements with alternative suppliers.

As part of their manufacture of our product candidates, our CMOs and third-party suppliers are expected to comply with and respect the intellectual property and proprietary rights of others. If a CMO or third-party supplier fails to acquire the proper licenses or otherwise infringes, misappropriates or otherwise violates the intellectual property or the proprietary rights of others in the course of providing services to us, we may have to find alternative CMOs or third-party suppliers or defend against claims of infringement, either of which would significantly impact our ability to develop, obtain regulatory approval for, or commercialize our product candidates, if approved.

In addition, given our limited experience in developing and commercializing companion diagnostics, we do not plan to develop companion diagnostics internally and thus will be dependent on the sustained cooperation and effort of third-party collaborators in developing and obtaining approval for companion diagnostics if required. Reliance on these third-party collaborators exposes us to risks due to our limited control of their activities, including compliance by them with cGMP regulations or similar foreign requirements and inspection of their manufacturing facilities by the FDA or comparable foreign regulatory authorities and their obtaining, maintaining and protecting their intellectual property rights necessary to develop and manufacture companion diagnostics while not infringing on the intellectual property rights of others. We or our third-party collaborators also will need to source raw materials for any companion diagnostics, including obtaining amounts sufficient for widespread adoption of testing and a potential commercial launch of RLYB212, if approved, and we may be dependent on our collaborators to identify and obtain reliable sources of raw materials. Our collaborators also may breach their agreements with us or otherwise fail to perform to our satisfaction, which could impact the development timeline of our product candidates, and we may incur additional costs and delays if we need to transition to a new third-party companion diagnostic partner.

We rely, and will continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials. If we fail to effectively oversee and manage these third parties, if they do not successfully carry out their contractual duties, or if they perform in an unsatisfactory manner, it may harm our business.

We rely, and will continue to rely, on CROs, CRO-contracted vendors, and clinical trial sites to ensure the proper and timely conduct of our clinical trials. Our reliance on CROs for clinical development activities limits our control over these activities, but we remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory, and scientific standards.

We and our CROs will be required to comply with the GLP requirements for our preclinical studies and GCP requirements for our clinical trials. Regulatory authorities enforce GCP requirements through periodic inspections of trial sponsors, principal investigators, and clinical trial sites. If we, or our CROs, fail to comply with GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or other comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements

and may require a large number of patients. Our failure or any failure by our CROs, investigators, CMOs or other third parties to comply with regulatory requirements or to recruit enough patients may delay ongoing or planned clinical trials or require us to repeat clinical trials, which would delay the regulatory approval process. Failure by us or by third parties we engage to comply with regulatory requirements can also result in fines, adverse publicity, and civil and criminal sanctions. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Our CROs, vendors and clinical trial investigators are not our employees, and we do not control whether they devote sufficient time and resources to our clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities, which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs and other third parties involved in our preclinical studies and clinical trials, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs and other third parties involved in our trials do not successfully carry out their contractual duties or obligations, or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, any product candidates that we develop. As a result, our financial results and the commercial prospects for any product candidates that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If our relationship with any CROs terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition, and prospects.

Risks Related to Healthcare Laws and Other Legal Compliance Matters

Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates, if approved, and may affect the prices we may set.

In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes, and additional proposed changes, to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of health care. For example, in March 2010, the ACA was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. The ACA expanded health care coverage through a Medicaid expansion and the implementation of the individual mandate for health insurance coverage. The ACA also imposed an annual fee payable on manufacturers of branded prescription drugs and biologic agents (other than those designated as orphan drugs) and included changes to the coverage and reimbursement of drug products under government healthcare programs. Such changes included an expansion in the Medicaid drug rebate program and an increase in the statutory minimum rebates a manufacturer must pay under the program as well as a new Medicare Part D coverage gap discount program requiring manufacturers to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period in exchange for coverage of the drugs under Medicare Part D.

Beyond the ACA, there have been ongoing healthcare reform efforts. Drug pricing and payment reform was a focus of the Trump Administration and has been a focus of the Biden Administration. For example, federal legislation enacted in 2021 eliminates a statutory cap on Medicaid drug rebate program rebates effective January 1, 2024. As another example, the Inflation Reduction Act ("IRA") of 2022 includes a number of changes intended to address rising prescription drug prices in Medicare Parts B and D, with varying implementation dates. These changes include caps on Medicare Part D out-of-pocket costs, Medicare Part B and Part D drug price inflation rebates, a new Medicare Part D manufacturer discount drug program (replacing the ACA

Medicare Part D coverage gap discount program) and a drug price negotiation program for certain high spend Medicare Part B and Part D drugs (with the first list of drugs announced in 2023). Subsequent to the enactment of the IRA, in 2022, the Biden administration released an executive order directing the U.S. Department of Health and Human Services ("HSS") to report on how the Center for Medicare and Medicaid Innovation (“CMMI”) could be leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. The report was issued in 2023 and proposed various models that CMMI is currently developing which seek to lower the cost of drugs, promote accessibility, and improve quality of care. One model would adjust Part B payments for drugs approved by FDA under the accelerated approval pathway to encourage timely confirmatory trial completion.

Healthcare reform efforts have been and may continue to be subject to scrutiny and legal challenge. For example, with respect to the ACA, tax reform legislation was enacted that eliminated the tax penalty established for individuals who do not maintain mandated health insurance coverage beginning in 2019 and, in 2021, the U.S. Supreme Court dismissed the latest judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. As another example, revisions to regulations under the federal anti-kickback statute would remove protection for traditional Medicare Part D discounts offered by pharmaceutical manufacturers to pharmacy benefit managers and health plans. Pursuant to court order, the removal was delayed and recent legislation imposed a moratorium on implementation of the rule until January 2032. As another example, the IRA drug price negotiation program has been challenged in litigation filed by various pharmaceutical manufacturers and industry groups.

There have also been efforts by federal and state government officials or legislators to implement measures to regulate prices or payment for pharmaceutical products, including legislation on drug importation. Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, at the federal level, there have been administration initiatives, Congressional inquiries and proposed federal and state legislation designed to bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient assistance programs and reform government program reimbursement methodologies for drugs.

Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing.

Adoption of new legislation at the federal or state level could affect demand for, or pricing of, any future products if approved for sale. We cannot, however, predict the ultimate content, timing or effect of any changes to the ACA or other federal and state reform efforts. There is no assurance that federal or state health care reform will not adversely affect our future business and financial results.

General legislative cost control measures may also affect reimbursement for our product candidates. The Budget Control Act, as amended, resulted in the imposition of reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect through 2032 unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

In markets outside of the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we, or any third parties we may engage, are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Our business operations and current and future relationships with contractors, investigators, healthcare professionals, consultants, third-party payors, patient organizations, customers, and others will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with contractors, investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our product candidates, if approved. Such laws, some of which may apply only after our products are approved for marketing, include:

- U.S. federal false claims, false statements and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid;

- U.S. federal healthcare program anti-kickback law, which prohibits, among other things, persons from offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for, or the purchasing or ordering of, a good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid;

- U.S. HIPAA which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- U.S. FDCA, which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing such products prior to approval or for off-label use and regulates the distribution of samples;

- U.S. federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;

- U.S. federal Open Payments (or federal “sunshine” law), which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with certain healthcare providers to CMS for re-disclosure to the public, as well as ownership and investment interests held by physicians and their immediate family members;

- U.S. federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws; state laws requiring pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers or report information related to payments to health care providers, marketing expenditures or drug prices; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing privacy, security, and breaches of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;

- U.S. laws and regulations prohibiting bribery and corruption, such as the FCPA, which, among other things, prohibits U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations or foreign government-owned or affiliated entities, candidates for foreign public office, and foreign political parties or officials thereof; and

- similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of personal information, such as, where applicable, the GDPR which imposes obligations and restrictions on the collection, use, and disclosure of personal data relating to individuals located in the EU and the EEA (including health data). See "—Our business operations may subject us to data protection laws, including the GDPR, the UK GDPR, the CCPA and other similar laws."

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare and other laws and regulations will involve substantial costs. Given the breadth of the laws and regulations and narrowness of any exceptions, limited guidance for certain laws and regulations and evolving government interpretations of the laws and regulations, regulatory authorities may possibly conclude that our business practices may not comply with healthcare laws and regulations, including our consulting agreements and other relationships with healthcare providers.

If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to actions including the imposition of civil, criminal, and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements, or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Further, defending against any such actions can be costly, time consuming, and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Our business operations may subject us to data protection laws, including the GDPR, the UK GDPR, the CCPA and other similar laws. The GDPR and UK GDPR apply to companies established in the EEA and UK, respectively, as well as to companies that are not established in the EEA or UK, respectively, and which collect and use personal data in relation to (i) offering goods or services to, or (ii) monitoring the behavior of, individuals located in the EEA or UK, respectively. If we conduct clinical trial programs in the EEA or UK (whether the trials are conducted directly by us or through a clinical vendor or collaborator) or enter into research collaborations involving the monitoring of individuals in the EEA or UK, or market our products to individuals in the EEA or UK, we will be subject to the GDPR or UK GDPR, as applicable. The GDPR and UK GDPR put in place stringent operational requirements for processors and controllers of personal data, including, for example, high standards for obtaining consent from individuals to process their personal data (or reliance on another appropriate legal basis), the provision of robust and detailed disclosures to individuals about how personal data is collected and processed (in a concise, intelligible and easily accessible form), an individual data rights regime (including access, erasure, objection, restriction, rectification and portability), maintaining a record of data processing, data export restrictions governing transfers of data from the EEA and UK, respectively, short timelines for data breach notifications to be given to data protection regulators or supervisory authorities (and in certain cases, affected individuals) of data breaches, and limitations on retention of information. The GDPR and UK GDPR also put in place increased requirements pertaining to health data and other special categories of personal data, as well as a definition of pseudonymized (i.e., key-coded) data. Further, the GDPR provides that EEA member states may establish their own laws and regulations limiting the processing of genetic, biometric, or health data, which could limit our ability to collect, use, and share such data and/or could cause our costs to increase. In addition, there are certain obligations if we contract third-party processors in connection with the processing of personal data. If our or our collaborators' or service providers' privacy or data security measures fail to comply with the GDPR or UK GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data, or fines of up to 20 million Euros in the case of GDPR or £17.5 million in the case of UK GDPR or, in each case, up to 4% of our total worldwide annual revenue of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, including class-action type litigation, negative publicity, reputational harm and a potential loss of business and goodwill.

Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA and the UK to the United States. Most recently, on July 16, 2020, the Court of Justice of the European Union (the "CJEU") invalidated the EU-US Privacy Shield Framework (the "Privacy Shield") under which personal data could be transferred from the EEA to US entities who had self-certified under the Privacy Shield scheme. This framework has been replaced by the E.U.-U.S. Data Privacy Framework, for which the European Commission adopted an adequacy decision in July 2023, and the UK-US Data Bridge, which took effect in October 2023. While we do not currently rely upon these frameworks, we expect there to be legal challenges to this framework in the future, which could draw into question the legitimacy of other cross-border transfer mechanisms, including the standard contractual clauses on which we rely to transfer personal data from the EEA and UK to the U.S. and other jurisdictions. On June 4, 2021, the European Commission released two revised sets of standard contractual clauses for transfers of personal data from the EEA to the U.S. and has indicated that it will release additional revised standard contractual clauses in the near future.

These recent developments may require us to review and amend the legal mechanisms by which we make and/ or receive personal data transfers to/ in the United States. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results. Other countries outside of the EEA and UK maintain different privacy laws that we are subject to which may further increase our costs of compliance and expose us to greater legal risk.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. While we do not believe that we are directly subject to HIPAA as either a “covered entity” or “business associate,” U.S. sites at which we conduct clinical trials are likely to be covered entities and thus must ensure that they obtain adequate patient authorization or establish another basis under HIPAA to disclose a clinical trial subject’s individually identifiable health information to us and other entities participating in our clinical trials.

In the United States, the CCPA came into effect in January 2020 and was expanded by the California Privacy Rights Act, which took effect on January 1, 2023 (collectively, “CCPA”), and which, collectively, (i) requires certain disclosures to California individuals; (ii) increases the privacy and security obligations of entities handling certain personal information; and (iii) affords such individuals, in certain situations, abilities to request the erasure of personal information, opt out of certain sales of personal information, opt out of the “sharing” of personal information (*i.e.*, disclosing of personal information for cross-context behavioral advertising), and limit the use and disclosure of “sensitive personal information” for purposes other than those for which it was disclosed, among others. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Because we have not yet generated revenue and do not meet the CCPA’s other jurisdictional tests, we do not yet meet the applicable threshold for the CCPA to apply to our business. If our business becomes subject to CCPA in the future, it could increase our compliance costs and potential liability. Similar laws have been proposed or passed in more than half of the states in the U.S. and in the U.S. Congress. Furthermore, all fifty U.S. states, the District of Columbia, Puerto Rico, and other U.S. territories have enacted data breach notification laws that require, among other things, notifications to state governments and/or the affected individuals in the event of a data breach, which differ from one another and impose significant compliance burden. As such, we will need to review periodically our operations in comparison to developments in such laws. Achieving and sustaining compliance with applicable international, federal and state privacy, security, and breach reporting laws may prove time-consuming and costly.

We are subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.
Our operations, including our development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release, and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds, and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, the production efforts of our third-party manufacturers or our development efforts may be interrupted or delayed.

Risks Related to Our Intellectual Property

If we are unable to obtain, maintain and enforce patent protection for our technology and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected.
Our success depends in large part on our ability to obtain and maintain protection of the intellectual property we may own solely and jointly with others, or may license from others, particularly patents, in the United States and other countries with respect to any proprietary technology and product candidates we develop. We seek to protect our proprietary position by filing patent applications in the United States and select other countries related to our technologies and product candidates that are important to our business and by in-licensing intellectual property related to such technologies and product candidates. If we are unable to obtain or maintain patent protection in jurisdictions important to our business with respect to any proprietary technology or product candidate, our business, financial condition, results of operations and prospects could be materially harmed.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, defend or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. In some circumstances involving technology that we license from third parties, we do not have the sole right to control the preparation, filing and prosecution of patent applications or to maintain, enforce and defend the in-licensed patents. Therefore, these in-licensed patents and applications may not be prepared, filed, prosecuted, maintained, defended and enforced in a manner consistent with the best interests of our business.

The patent rights of pharmaceutical and biotechnology companies generally are highly uncertain, involve complex legal and factual questions and have been the subject of much litigation in recent years. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged in the United States or in numerous foreign jurisdictions. Various courts, including the U.S. Supreme Court, have rendered decisions that affect the scope of patent eligibility of certain inventions or discoveries relating to biotechnology. These decisions conclude, among other things, that abstract ideas, natural phenomena and laws of nature are not themselves patent eligible subject matter.

Precisely what constitutes a law of nature or abstract idea is uncertain, and certain aspects of our technology could be considered ineligible for patenting under applicable law. In addition, the scope of patent protection outside the United States is uncertain, and laws of foreign countries may not protect our rights to the same extent as the laws of the United States or vice versa. For example, European patent law precludes the patentability of methods of treatment of the human body. With respect to both owned and in-licensed patent rights, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents that protect our technology and product candidates, in whole or in part, in any particular jurisdiction

or whether the claims of any issued patents will provide sufficient protection from competitors. Changes in either the patent laws or interpretation of the patent laws in the United States or other countries may diminish the value of our patents and our ability to obtain, protect, maintain, defend and enforce our patent rights, narrow the scope of our patent protection and, more generally, affect the value or narrow the scope of our patent rights.

Further, third parties may have intellectual property rights relating to our product candidates of which we are unaware. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases are not published at all. Therefore, neither we nor our licensors can know with certainty whether either we or our licensors were the first to make the inventions claimed in the patents and patent applications we own or in-license now or in the future, or that either we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our owned and in-licensed patent rights are uncertain.

We, or our licensors, may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office (“USPTO") or become involved in opposition, derivation, revocation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others in the United States and/or foreign countries. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. If the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Additionally, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if our owned and in-licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and in-licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such challenges also may result in substantial cost and require significant time from our management and employees, even if the eventual outcome is favorable to us. Furthermore, our competitors may be able to circumvent our owned or in-licensed patents by developing similar or alternative technologies or products in a non-infringing manner. For these reasons, our owned and in- licensed patent portfolio may not provide us with sufficient rights to exclude others from using or commercializing technology and products similar or identical to any of our technology and product candidates for any period of time.

Patent terms may not protect our competitive position for an adequate amount of time.
Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are approved for use or commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours during periods when commercial exclusivity would be valuable to us.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, which if granted could extend the term of our marketing exclusivity for any product candidates we may develop, our business may be materially harmed.
In the United States, the term of a patent that covers an FDA-approved drug may be eligible for limited PTE which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-

Waxman Act, permits a PTE of up to five years beyond the expiration date of the patent. The length of the PTE is related to the length of time the drug is under regulatory review. A PTE cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. In addition, the patent term of only one patent applicable to an approved drug may be extended, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar provisions are available in Europe and certain other non-United States jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, if and when our product candidates receive FDA approval, we expect to apply for PTEs on patents covering those product candidates, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted and, even if granted, the length of such extensions. We may not be granted PTE either in the United States or in any foreign country, even where that patent is eligible for PTE, if, for example, we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the regulatory authority could be less than we request. If we obtain such an extension, it may be for a shorter period than we had sought. If we are unable to obtain any PTE or the term of any such extension is less than we request, our competitors may obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations and prospects could be materially harmed.

Furthermore, for any future licensed patents, we may not have the right to control prosecution, including filing with the USPTO or any foreign agency, of a petition for PTE under the Hatch-Waxman Act or analogous foreign provisions. Thus, for example, if one of our licensed patent applications, if granted, is eligible for PTE under the Hatch-Waxman Act, we may not be able to control whether a petition to obtain a PTE is filed or obtained from the USPTO.

Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of patent laws in the United States or other jurisdictions, including patent reform legislation such as the U.S. Leahy-Smith America Invents Act (the "Leahy-Smith Act") could increase the uncertainties and costs surrounding the prosecution of our owned and in-licensed patent applications and the maintenance, enforcement or defense of our owned and in-licensed issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These changes include provisions that switched the United States from a first- to-invent system to a first-inventor-to-file system, affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents and enable third-party submission of prior art to the USPTO during patent prosecution, and provide additional procedures to attack the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Assuming that other requirements for patentability are met, under the Leahy-Smith Act and pursuant to foreign laws outside of the United States, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. Such laws could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has increased uncertainty with respect to the validity and enforceability of patents once obtained. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

We may become involved in lawsuits to protect or enforce our patent or other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors and other third parties may infringe, misappropriate or otherwise violate patents or other intellectual property that we or our licensors may own, obtain or acquire. As a result, we or our licensors may need to file

infringement, misappropriation or other intellectual property claims, which can be expensive and time-consuming. Any claims we assert against others could provoke them to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property rights.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. In a patent infringement proceeding, the perceived infringers could counterclaim that the patents we or our licensors have asserted are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are common. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may institute such claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions, such as opposition proceedings in the European Patent Office. The outcomes of allegations of invalidity or unenforceability are unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art of which the patent examiner and we or our licensing partners were unaware during prosecution.

An adverse result in any such proceeding could put one or more of our current or future owned or in- licensed patents at risk of being invalidated or interpreted narrowly and could put any of our owned or in- licensed patent applications at risk of not yielding an issued patent. A court may also refuse to stop the third-party from using the technology at issue in a proceeding, for example, on the basis that our owned or in-licensed patents do not cover that technology. Furthermore, if the breadth or strength of protection provided by our current or future patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products, diagnostic tests, or services.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference or derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information or trade secrets could be compromised by disclosure during litigation. Any of the foregoing could allow third parties to develop and commercialize competing technologies and products and have a material adverse impact on our business, financial condition, results of operations and prospects.

Third parties may allege that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. There is considerable patent and other intellectual property litigation in the pharmaceutical and biotechnology industries. We may become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and product candidates, including interference proceedings, post grant review, inter partes review and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, including our competitors, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our

technologies or product candidates may be subject to claims that they infringe the patent rights of third parties. Our competitors and others may have significantly larger and more mature patent portfolios than we have. In addition, future litigation may be initiated by patent holding companies or other adverse patent owners who have no relevant product or service revenue and against whom our own patents may provide little or no deterrence or protection. Competitors may also assert that our product candidates infringe their intellectual property rights as part of a business strategy to impede our successful entry into those markets.

The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources and management attention to defend. The risks of being involved in such litigation and proceedings may increase if and as our product candidates near commercialization and as we gain greater visibility as a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of merit. Because patent applications can take many years to issue, pending patent applications may result in issued patents that our product candidates infringe. For example, there may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the discovery, use or manufacture of our product candidates or technologies. We may not be aware of all such intellectual property rights potentially relating to our technology and product candidates, or we may incorrectly conclude that third-party intellectual property is invalid or that our activities and product candidates do not infringe the intellectual property rights of third parties. Thus, we do not know with certainty that our technology and product candidates, or our development and commercialization thereof, do not and will not infringe, misappropriate or otherwise violate any third-party's intellectual property rights.

A court could hold that third-party patents are valid, enforceable and infringed. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one that requires us to present clear and convincing evidence as to the invalidity of the claims of any such U.S. patent, there is no assurance that a court would invalidate the claims of any such U.S. patent.

Parties making claims against us may obtain injunctive or other equitable relief. For example, if any third-party patents were held to cover the manufacturing process of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidates. In the event of a successful claim of infringement against us, we may also have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, indemnify customers, collaborators or other third parties, seek new regulatory approvals, and redesign our infringing products, which may not be possible or practical. If we are found to infringe, misappropriate or otherwise violate a third-party's intellectual property rights, we may be required to obtain a license from such third-party to continue developing, manufacturing and marketing our technology and product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property litigation or other legal proceedings relating to intellectual property could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities, which would impair our ability to pursue our business. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our adversaries may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and may also have an advantage in such proceedings due to their more mature and developed intellectual property portfolios.

Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could compromise our ability to compete in the marketplace.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance, renewal and annuity fees and various other government fees on any issued patent and pending patent application must be paid to the USPTO and foreign patent agencies in several stages or annually over the lifetime of our owned and in-licensed patents and patent applications. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application and prosecution process. In certain circumstances, we may rely on our licensing partners to pay these fees to, or comply with the procedural and documentary rules of, the relevant patent agency. With respect to our patents, we rely on an annuity service, outside firms, and outside counsel to remind us of the due dates and to make payment after we instruct them to do so. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to office actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market with similar or identical products or technology. If we or our licensors fail to maintain the current and future patents and patent applications covering our product candidates, our competitors might be able to enter the market with similar or identical products or technology, which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we are unable to obtain licenses from third parties on commercially reasonable terms, our business could be harmed.

In addition to our existing licensing agreements, it may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, if approved, in which case we would be required to obtain a license from these third parties. The in-licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to in-license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. In addition, we expect that competition for the in-licensing or acquisition of third-party intellectual property rights for product candidates that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs.

If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, such as substantial licensing or royalty payments, our business could be materially harmed. If we are unable to obtain a necessary license, the third parties owning such intellectual property rights could seek an injunction prohibiting our sales or we may be unable to otherwise develop or commercialize the affected product candidates, which could materially harm our business. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

If we are unable to obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and product candidates, which could harm our business, financial condition, results of operations, and prospects significantly.

If we fail to comply with our obligations in our intellectual property licenses with third parties, or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.

We are party to license agreements that impose, and we may enter into additional licensing and funding arrangements with third parties that may impose, among other things, diligence, development, and commercialization timelines, milestone payment, royalty, insurance and other obligations on us. Under our existing licensing agreements, including our license agreement with Affibody, we are obligated to pay

milestones and royalties on net product sales of product candidates or related technologies to the extent they are covered by the agreements. If we fail to comply with such obligations under current or future license and funding agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements, or our counterparties may require us to grant them certain rights. Such an occurrence could materially adversely affect the value of any product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, which would have a material adverse effect on our business, financial condition, results of operations, and prospects, or impede, delay or prohibit the further development or commercialization of, one or more product candidates that rely on such agreements.

Disputes may arise regarding intellectual property that is or becomes subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other matters of contract interpretation;
- whether and the extent to which our technology and processes infringe the intellectual property rights of the licensor that are not subject to the licensing agreement;
- whether our licensor or its licensor had the right to grant the license agreement;
- whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of the intellectual property rights without their authorization;
- our involvement in the prosecution of licensed patents and our licensors' overall patent enforcement strategy;
- the amounts of royalties, milestones or other payments due under the license agreement;
- the sublicensing of patent and other rights under collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If we do not prevail in such disputes, we may lose any or all of our rights under such license agreements.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected technology and product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Despite our efforts, our licensors or future licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize product candidates and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying intellectual property fails to provide the intended exclusivity, competitors could seek regulatory approval for and market products and technologies identical to ours. This could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

We may not be able to protect our intellectual property and proprietary rights throughout the world.
Third parties may attempt to develop and commercialize competitive products in foreign countries where we do not have any patent protection and/or where legal recourse may be limited. This may have a significant commercial impact on our foreign business operations.

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, and even where such protection is nominally available, adequate judicial and governmental enforcement of such intellectual property rights may be lacking. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling our inventions in such countries or importing products made using our inventions into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection or licenses, but enforcement is not as strong as that in the United States. These products may compete with our products, 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 pharmaceutical and biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, certain jurisdictions do not protect, to the same extent as the United States or at all, inventions that constitute new methods of treatment.

Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries, including India, China and certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business, financial condition, results of operations, and prospects may be adversely affected.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.
We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property as an inventor, co-inventor, owner or co-owner. For example, we or our licensors or collaborators may have inventorship or ownership disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' or collaborators' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors or collaborators fail in defending any such

claims, we may be required to pay monetary damages and we may also lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims by third parties asserting that our employees, consultants or contractors have wrongfully used or disclosed confidential information of such third parties, or that they have wrongfully used or disclosed alleged trade secrets of their current or former employers, or that we have misappropriated their intellectual property, or that they own what we regard as our own intellectual property.
Many of our employees, consultants and contractors were previously employed at or engaged by universities or other pharmaceutical or biotechnology companies, including our competitors or potential competitors. Many of them executed proprietary rights, non-disclosure and/or non-competition agreements in connection with such previous employment or engagement. Although we try to ensure that the individuals who work for us do not use the intellectual property rights, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or they have, inadvertently or otherwise, used, infringed, misappropriated or otherwise violated the intellectual property rights, or disclosed the alleged trade secrets or other proprietary information, of these former employers, competitors or other third parties. We may also be subject to claims that we have improperly used or obtained such trade secrets. Litigation may be necessary to defend against these claims. Any litigation or the threat of litigation may adversely affect our ability to hire employees or engage consultants and contractors. A loss of key personnel or their work product could hamper or prevent us from developing and commercializing products and product candidates, which could harm our business.

In addition, while it is our policy to require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in obtaining such an agreement from each party who in fact develops intellectual property that we regard as our own. Our intellectual property assignment agreements with them may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we fail in prosecuting or defending any such claims, we may be required to pay monetary damages, and we may also lose valuable intellectual property rights or personnel, which could have a material adverse effect on our competitive position and prospects. Such intellectual property rights could be awarded to a third-party, and we could be required to obtain a license from such third-party to commercialize our technology or products, which license may not be available on commercially reasonable terms, or at all, or such license may be non-exclusive. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and employees.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.
In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information to maintain our competitive position. We seek to protect our trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality agreements with our employees and consultants. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology. 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. Detecting the disclosure or misappropriation of a trade secret and enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. 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, or those to whom they communicate such trade secrets, from using that technology or information to compete with us.

Furthermore, we expect that, over time, our trade secrets, know-how and proprietary information may be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel to and from academic and industry scientific positions. Consequently, without costly efforts to protect our proprietary technology, we may be unable to prevent others from exploiting that technology, which could affect our ability to expand in domestic and international markets. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third-party, our competitive position would be materially and adversely harmed.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. These security measures may be breached, and we may not have adequate remedies for any breach.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these trademarks or trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trademarks or trade names similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trademark or trade name infringement claims brought by owners of other registered trademarks or trade names that incorporate variations of our trademarks or trade names. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks and trade names may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain a competitive advantage. For example:

- we or our license partners or current or future collaborators might not have been the first to file patent applications covering our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or in-licensed intellectual property rights;
- it is possible that our owned and in-licensed pending patent applications or those we may own or in-license in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors or other third parties 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 cannot ensure that any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product candidates;

- we cannot ensure that any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable product candidates or will provide us with any competitive advantages;
- we cannot ensure that our commercial activities or product candidates will not infringe upon the patents of others;
- we cannot ensure that we will be able to successfully commercialize our product candidates on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to seek patent protection in order to maintain certain trade secrets or know-how, and a third-party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Our Employees, Managing Our Growth and Our Operations

Our workforce reduction and portfolio prioritization announced in February 2024 may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.
In February 2024, we announced a workforce reduction of approximately 45% in connection with a prioritization of our portfolio and cost savings plan to focus on our clinical assets. We cannot guarantee that we will not undertake additional workforce reductions or restructuring activities in the future. Our updated operating plan may be disruptive to our operations and our workforce reductions may result in unanticipated consequences, including increased employee attrition, difficulties executing our day-to-day operations and reduced employee morale. In addition, there could be unforeseen expenses associated with our updated plan, and we could incur unanticipated charges or liabilities. As a result, we may not realize the expected cost savings or other benefits of such actions, which could have an adverse effect on our business, operating results and financial condition.

Our future success depends on our ability to retain our key personnel and to attract, retain and motivate qualified personnel.
We are highly dependent on the expertise of the principal members of our management, scientific, and clinical teams. Our scientific and clinical development personnel have extensive experience developing and implementing novel clinical trial designs and successfully conducting clinical trials in never-before treated patient populations. If we lose one or more of our executive officers or key employees, our ability to execute our programs and implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize product candidates successfully.

Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel on acceptable terms given the competition among numerous biotechnology and pharmaceutical companies for similar personnel. We may also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

Many of our employees were previously employed by Alexion (now part of AstraZeneca), a potential competitor. To the extent we employ or engage personnel from competitors, we may be subject to allegations that such individuals have been improperly solicited or have divulged proprietary or other confidential information, or that their former employers own their research output.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may

be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

If employees who were not impacted by the workforce reduction seek alternate employment, we may have to increase reliance on external support to advance our operations. Any workforce reductions could also harm our ability to attract and retain qualified management, scientific, clinical, and manufacturing personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing our product candidates in the future.

We expect to expand our development, regulatory, and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities or lease or acquire new facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our computer systems, as well as those of our CROs and other contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural and manmade disasters (including hurricanes), terrorism, war, and telecommunication and electrical failures. While we do not believe that we have experienced any such system failure or accident to date, if such an event were to occur and cause interruptions in our or their operations, it could result in delays and/or material disruptions of our research and development programs. For example, the loss of preclinical or clinical trial data from completed, ongoing, or planned trials, or the loss of other proprietary data, could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we currently rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability, and the development of our product candidates could be delayed.

Our proprietary or confidential information may be lost, or we may suffer security breaches.

The U.S. federal and various state and foreign governments have enacted or proposed requirements regarding the collection, distribution, use, security and storage of personally identifiable information and other data relating to individuals. In the ordinary course of our business, we and third parties with which we have relationships will continue to collect and store sensitive data, including clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, in data centers and on networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our and our collaborators' security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or internal bad actors, breaches due to employee error, technical vulnerabilities, malfeasance, or other disruptions.

Several proposed and enacted federal, state and international laws and regulations obligate companies to notify individuals of security breaches involving personally identifiable information, which could result from breaches experienced by us or by third parties, including collaborators, vendors, contractors, or other organizations with which we have formed strategic relationships. Although, to our knowledge, neither we nor any such third parties have experienced any material security breach, and even though we may have contractual protections with such third parties, any such breach could compromise our or their networks and the information stored therein could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure, notifications, follow-up actions related to such a security breach or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and significant costs, including regulatory penalties, fines, and legal expenses, and such an event could disrupt our operations, cause us to incur remediation costs, damage our reputation, and cause a loss of confidence in us and our or such third parties'

ability to conduct clinical trials, which could adversely affect our reputation and delay the clinical development of our product candidates.

Risks Related to Our Common Stock

An active trading market for our common stock may not be sustained.
If a market for our common stock is not sustained, it may be difficult for you to sell your shares of common stock at an attractive price or at all. We cannot predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations may be below the expectations of public market analysts and investors, and, as a result of these and other factors, the price of our common stock may fall.

The market price of our common stock may be volatile, which could result in substantial losses for investors.
Shares of our common stock were offered in our IPO in July 2021 at a price of $13.00 per share and between the date of our initial public offering ("IPO") and March 7, 2024, the closing price per share of our common stock has ranged from as low as $1.25 to as high as $23.40. Some of the factors that may cause the market price of our common stock to fluctuate include:

- the success of existing or new competitive product candidates or technologies;
- the timing and results of preclinical studies for any product candidates that we may develop;
- failure or discontinuation of any of our product development and research programs;
- the success of the development of companion diagnostics, if required, for use with our product candidates;
- results of preclinical studies, clinical trials, or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
- commencement or termination of collaborations for our product development and research programs;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents, or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our research programs or product candidates that we may develop;
- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines, or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders;
- expiration of market stand-off or lock-up agreement;
- effects of public health crises, pandemics and epidemics, such as COVID-19;

- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry, and market conditions; and
- the other factors described in this “Risk Factors” section and elsewhere in this Annual Report on Form 10-K.

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. Following periods of such volatility in the market price of a company’s securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future.

If securities analysts stop publishing research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock is influenced in part on the research and reports that industry or financial analysts publish about us or our business. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Moreover, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline.

A significant portion of our total outstanding shares may be sold into the market, which could cause the market price of our common stock to decline significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. As of March 7, 2024, we have 37,811,970 shares of common stock outstanding. All of these shares may be resold in the public market immediately, unless held by our affiliates who are subject to volume limitations under Rule 144. As of March 7, 2024, we also have pre-funded warrants to purchase up to an aggregate of 3,333,388 shares of common stock outstanding. We may not effect the exercise of any pre-funded warrant, and a holder will not be entitled to exercise any portion of any pre-funded warrant if, upon giving effect to such exercise, the aggregate number of shares of common stock beneficially owned by the holder (together with its affiliates) would exceed 9.99% of the number of shares of common stock outstanding immediately after giving effect to the exercise, which percentage may be increased or decreased at the holder’s election upon 61 days’ notice to us subject to the terms of such pre-funded warrants, provided that such percentage may in no event exceed 19.99%.

Moreover, as of December 31, 2023, certain holders of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. On May 9, 2023, we registered an aggregate of 12,351,600 shares of common stock held by holders with registration rights, for resale, pursuant to a registration statement on Form S-3. In addition, we have entered into the Sales Agreement with Cowen to offer and sell shares of our common stock having an aggregate offering price of up to $100,000,000, from time to time, through an at-the-market offering program. We also registered an aggregate of 9,929,767 shares of common stock that we may issue under our equity compensation plans or that are issuable upon exercise of outstanding options. These shares can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

Insiders have substantial influence over us, which could limit your ability to affect the outcome of key transactions, including a change of control.

Our directors and executive officers and their affiliates beneficially own shares representing approximately 37% of our outstanding common stock as of March 7, 2024. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. The interests of these holders may not always coincide with our corporate interests or the interests of other stockholders, and they may act in a manner with which you may not agree or that may not be in the best interests of our other stockholders. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against companies following a decline in the market price of their securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant share price volatility in recent years. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain on an investment in our common stock in the foreseeable future.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act and we may remain an emerging growth company until December 31, 2026. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 ("SOX Section 404"), not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period, or (ii) no longer qualify as an emerging growth company. Therefore, the reported results of operations contained in our financial statements may not be directly comparable to those of other public companies.

Provisions in our amended and restated certificate of incorporation, our amended and restated bylaws and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Our amended and restated certificate of incorporation and bylaws include provisions that:

- authorize “blank check” preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may be removed only for cause;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize our board of directors to modify, alter or repeal our amended and restated bylaws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our amended and restated certificate of incorporation and amended and restated bylaws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock.

In addition, because we are incorporated in the State of Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware (the "DGCL") which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated certificate of incorporation designates the state or federal courts within the State of Delaware as the exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, subject to limited exceptions, the state or federal courts (as appropriate) within the State of Delaware are exclusive forums for (1) any derivative action or

proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against us arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws, (4) action against us or any of our directors or officers involving a claim or defense arising pursuant to the Exchange Act or the Securities Act, or (5) any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation described above. This exclusive forum provision does not apply to claims which are vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery of the State of Delaware, or for which the Court of Chancery of the State of Delaware does not have subject matter jurisdiction. For instance, the provision does not apply to actions arising under federal securities laws, including suits brought to enforce any liability or duty created by the Exchange Act or the rules and regulations thereunder. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our amended and restated certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our federal forum provision. If the federal forum provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The federal forum provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid.

General Risks

A variety of risks associated with operating internationally could materially adversely affect our business.
Our business strategy includes potentially expanding internationally. Doing business internationally involves several risks, including, but not limited to:

- multiple, conflicting, and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, economic sanctions laws and regulations, employment laws, regulatory requirements, and other governmental approvals, permits, and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors, or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products, and exposure to foreign currency exchange rate fluctuations;

- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade, and other business restrictions;
- certain expenses, including, among others, expenses for travel, translation, and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the FCPA its books and records provisions, or its anti-bribery provisions, as well as other applicable laws and regulations prohibiting bribery and corruption.

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

U.S. federal income tax reform could adversely affect our business and financial condition.
The rules dealing with U.S. federal, state, and local income taxation are constantly under review through the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect 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, (the "TCJA"), was enacted in 2017 and significantly reformed the Code. The TCJA, among other things, contains significant changes to corporate and individual taxation, some of which could adversely impact an investment in our common stock. On March 27, 2020, former President Trump signed into law the CARES Act, which included certain changes in tax law intended to stimulate the U.S. economy in light of the COVID-19 pandemic, including temporary beneficial changes to the treatment of NOLs, interest deductibility limitations and payroll tax matters. There also may be technical corrections legislation or other legislative changes proposed with respect to the TCJA and CARES Act, the effects of which cannot be predicted and may be adverse to us or our stockholders. Additionally, the IRA was enacted in August 2022.

Among other things, the IRA implemented a one percent (1%) excise tax on certain repurchases (including redemptions) of stock by publicly traded domestic corporations, and a corporate alternative minimum tax of fifteen percent (15%) on book income of certain large corporations. Future changes in tax laws could have a material adverse effect on our business, cash flows, financial condition or results of operations. In particular, proposed tax legislation could result in significant changes in, and uncertainty with respect to, tax legislation, regulation and government policy directly affecting our business or indirectly affecting us because of impacts on our customers and suppliers. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

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

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- significant costs to defend the litigation;
- distraction of management’s attention from our primary business;
- substantial monetary awards to patients or other claimants;

- inability to commercialize a product candidate;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased market demand for any product; and
- loss of revenue.

The clinical trial and product liability insurance we currently carry, and any additional clinical trial and product liability insurance coverage we acquire in the future, may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for any product candidate, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful clinical trial or product liability claim, or series of claims, brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operation and business, including preventing or limiting the commercialization of any product candidates we develop.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn, period of sustained increased inflation, or additional global financial crises, could result in a variety of risks to our business, including weakened demand for our product candidates, if approved, or our ability to raise additional capital when needed on acceptable terms, if at all. For example, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets. Further, geopolitical instability outside the United States may also impact our operations or affect global markets, such as the recent invasion of Ukraine by Russia and the Israel-Hamas war. While we do not currently conduct clinical trials in the Ukraine, Russia, or the Middle East, we cannot be certain what the overall impact of these events will be on our business or on the business of any of our third-party partners, including our contract research organizations, contract manufacturers or other partners. The impact of these events could also expand into other markets where we do business. A weak or declining economy could strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which current geopolitical tensions, the economic climate and the financial market conditions could adversely impact our business.

We have incurred, and will incur increased costs as a result of operating as a public company, and our management will continue to be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we have incurred, and particularly after we are no longer an “emerging growth company,” we will incur significant legal, accounting, and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Select Market, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect that we will need to hire additional accounting, finance, and other personnel in connection with our efforts to comply with the requirements of being, a public company, and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that the rules and regulations applicable to us as a public company may make it more difficult and more expensive for us to obtain director and officer liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors. We are currently evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to SOX Section 404, we are required to furnish a report by our management on our internal control over financial reporting with our Annual Report on Form 10-K with the SEC. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with SOX Section 404, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude that our internal control over financial reporting is effective as required by SOX Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk Management and Strategy

We have developed and implemented a cybersecurity risk management program that is designed to identify, assess and manage material risks from cybersecurity threats and to protect the security, confidentiality, integrity, and availability of our critical systems and information. Our information security program is developed using industry standards and best practices as a guide, including the National Institute of Standards and Technology (“NIST”) Cybersecurity Framework. The program includes penetration tests and periodic vulnerability scans, and evaluations by external service providers. The results of these evaluations are shared with senior management and the audit committee of the board of directors, where appropriate.

Our cybersecurity risk management program is integrated into our overall enterprise risk management processes and shares common methodologies, reporting channels and governance processes that apply across our enterprise risk management processes to other legal, compliance, strategic, operational, and financial risk areas.

Our cybersecurity risk management program includes:

- Risk assessments designed to help identify material cybersecurity risks to our critical systems, information, product candidates and our broader enterprise IT environment.
- A team principally responsible for managing: (a) our cybersecurity risk assessment processes, (b) our security controls, and (c) our response to cybersecurity incidents.
- The use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security controls as part of our operational security model.
- Threat intelligence that informs our third party IT service provider and us about new vulnerabilities and risks that require timely intervention or remediation.
- Cybersecurity awareness training of our employees, incident response personnel, and senior management.
- A cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents.

As of the date of this Annual Report on Form 10-K, we have not experienced a cybersecurity incident that resulted in a material effect on our business strategy, results of operations, or financial condition, but we cannot provide assurance that we will not be materially affected in the future by such risks or any future material incidents.

Governance

The audit committee of our board of directors has primary responsibility for oversight of our information security program. Our cyber security program is managed by our third party IT service provider together with internal

personnel. Our service provider and internal personnel work together to assess the environment, potential threats and responses.

Item 2. Properties.

Our corporate headquarters is located at 234 Church Street, Suite 1020, New Haven, CT 06510, where we lease and occupy 9,000 square feet of office space. The current term of our lease in New Haven expires September 30, 2025. We also lease 117 square feet of office space at 400 Farmington Avenue, Suite R2846, Farmington, CT 06032. The current term of our Farmington lease expires June 30, 2024. We believe that this office space is sufficient to meet our current needs. If required, we believe that suitable additional or alternative space would be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources, negative publicity and reputational harm and other factors.

Item 4. Mine Safety Disclosures.

Not Applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock began trade on the Nasdaq Global Select Market under the symbol "RLYB." Trading of our common stock commenced on July 29, 2021 in connection with our IPO. Prior to that time, there was no established public trading market for our common stock.

Stockholders

As of December 31, 2023, there were 32 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors our board of directors deems relevant, and subject to the restrictions contained in any future financing instruments. Our ability to pay cash dividends on our capital stock in the future may also be limited by the terms of any preferred securities we may issue or agreements governing any indebtedness we may incur.

Securities Authorized for Issuance Under Equity Compensation Plans

The information provided in the following table is as of December 31, 2023:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights and outstanding nonvested restricted stock units (1)	Weighted-average exercise price of outstanding options, warrants and rights (2)	Number of securities remaining available for future issuance under equity compensation plans (3)
Equity compensation plans approved by security holders	4,490,794	$ 9.98	3,157,110
Equity compensation plans not approved by security holders	—	—	—

(1) Reflects 4,270,544 shares of common stock to be issued upon exercise of outstanding options under our 2021 Equity Incentive Plan and 220,250 outstanding restricted stock units that were issued under the 2021 Equity Incentive Plan. This figure does not include 354,394 outstanding restricted stock awards that were issued under the 2021 Equity Incentive Plan.

(2) The weighted-average exercise price is calculated based on the exercise prices of outstanding options and does not include outstanding restricted stock units (which have no exercise price).

(3) Includes 2,284,232 shares available for future issuance under the 2021 Equity Incentive Plan and 872,878 shares available for future issuance under the 2021 Employee Stock Purchase Plan. The number of shares of our common stock delivered in satisfaction of awards under the 2021 Equity Incentive Plan will not be reduced by (i) any shares withheld by us in payment of the exercise price or purchase price of an award or in satisfaction of tax withholding requirements or (ii) any shares underlying any portion of an award that is settled in cash or that expires, becomes unexercisable, terminates or is forfeited to or repurchased by us without the delivery (or retention, in the case of restricted or unrestricted stock) of shares of our common stock. The number of shares available for delivery under the 2021 Equity Incentive Plan will not be increased by any shares that have been delivered under the 2021 Equity Incentive Plan and are subsequently repurchased using proceeds directly attributable to stock option exercises. In addition, the number of shares reserved for issuance under the 2021 Equity Incentive Plan automatically increases on January 1st of each year from 2022 to 2031 by the lesser of (i) five percent of the number of shares of the Company's common stock outstanding as of such date and (ii) the number of shares of the Company's common stock determined by the board of directors on or prior to such date. The number of shares reserved for issuance under the 2021 Employee Stock Purchase Plan automatically increases on January 1st of each year from 2022 to 2031 by the lesser of (i) one percent of the number of shares of the Company's common stock outstanding as of such date (ii) 582,648 shares of the Company's common stock, and (iii) the number of shares of the Company's common stock determined by the board of directors on or prior to such date (up to a maximum of 6,117,804 in the aggregate).

Use of Proceeds from Registered Securities

In August, 2021, we completed the IPO of our common stock pursuant to which we issued and sold 7,130,000 shares of our common stock, inclusive of 930,000 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $13.00 per share. The aggregate offering price of our IPO was $92.7 million.

The offer and sale of all of the shares of our common stock in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1, as amended (File No. 333-257655), which was declared effective by the SEC on July 28, 2021 and a registration statement on Form S-1MEF (File No. 333-258244), which was automatically effective upon filing with the SEC on July 28, 2021. Following the sale of all of the shares offered in connection with the closing of our IPO, the offering terminated. Jefferies LLC, Cowen and Company, LLC and Evercore Group L.L.C. acted as co-managers for the offering.

We received aggregate gross proceeds from our IPO of $92.7 million, or aggregate net proceeds of $83.0 million after deducting underwriting discounts and commissions and other offering costs. None of the underwriting discounts and commissions or offering costs were incurred or paid, directly or indirectly, to directors or officers of ours or their associates or to persons owning 10% or more of our common stock or to any of our affiliates.

Given our recent decision to prioritize our portfolio and reduce our expenses, we intend to use any remaining proceeds from our IPO primarily to support the development of RLYB212, working capital needs and general corporate purposes in support of the RLYB212 development program.

Item 6. Reserved

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 financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the section entitled "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K, our actual results could differ materially from the results described in or implied by the forward-

looking statements contained in the following discussion and analysis. See "Cautionary Note Regarding Forward-Looking Statements."

Our Business

We are a clinical-stage biotechnology company comprised of experienced biopharma industry leaders with extensive research, development, and rare disease expertise with a mission to develop and commercialize life-transforming therapies for patients with severe and rare diseases. Since our launch in January 2018, we have built a broad pipeline of promising product candidates aimed at addressing diseases with unmet medical need in the areas of maternal fetal health, complement dysregulation, hematology, and metabolic disorders. Our two most advanced programs are in clinical development: RLYB212, an anti-HPA-1a antibody for the prevention of FNAIT and RLYB116, an inhibitor of C5, with the potential to treat several diseases of complement dysregulation. Both programs have completed Phase 1 clinical trials, and we currently plan to initiate a Phase 2 clinical trial of RLYB212 in the second half of 2024.

Maternal Fetal Blood Disorders

RLYB212 is a monoclonal anti-HPA-1a antibody for the prevention of FNAIT, a potentially life-threatening rare hematological disease that impacts fetuses and newborns.

We have completed two RLYB212 clinical trials: a Phase 1 first-in-human clinical trial and a Phase 1b proof of concept clinical trial. The Phase 1 first-in-human clinical trial was a single-blind, placebo-controlled study that investigated the safety and PK of SC administration of RLYB212 in HPA-1a negative healthy participants. The clinical trial included a single dose cohort and a multiple dose cohort. In the multiple dose cohort, subjects received SC RLYB212 or placebo every 2 weeks for 12 weeks. We reported results from the multi-dose cohort in the fourth quarter of 2023. The data and our clinical pharmacology modeling predictions support a once monthly dosing regimen for the planned Phase 2 clinical trial.

In the first quarter of 2023, we announced RLYB212 achieved proof-of-concept in the Phase 1b trial. In this trial, subcutaneous RLYB212 administration produced a dose-dependent, rapid and complete elimination of transfused HPA-1a positive platelets in HPA-1a negative subjects, with both dose groups meeting the pre-specified proof-of-concept criteria of ≥ 90% reduction in mean platelet elimination half-life. Mean platelet elimination half-life was 5.8 hours (0.09mg dose) and 1.5 hours (0.29mg dose) for RLYB212 compared to 71.7 hours for placebo. In both Phase 1 trials, RLYB212 was well-tolerated with no reports of serious or severe adverse events.

Both the FDA and EMA have designated RLYB212 as an orphan drug. Orphan drug designations offer certain incentives including tax credits, marketing exclusivity upon any approval, fee waivers, and the ability to interact with both agencies to receive specialized regulatory advice and assistance. We recently engaged with the EMA in such a process in advance of our planned Phase 2 clinical trial. We received feedback from the EMA and are now moving forward with our Clinical Trial Application to support conduct of the Phase 2 study in Europe.

Based on the data from the clinical and preclinical programs and following planned discussions with regulatory authorities, we expect to initiate a Phase 2 dose confirmation study for RLYB212 in the second half of 2024. This study will be designed to confirm the RLYB212 dose regimen in expectant mothers at higher risk of FNAIT. Following completion of the Phase 2 dose confirmation study and consultation with regulatory authorities, we expect to initiate a Phase 3 registrational study.

We are also conducting a prospective, non-interventional, multinational FNAIT natural history study. This study is designed to screen up to 30,000 expectant mothers presenting at the Gestational Week 10 to 14 prenatal visit to determine the frequency of women at higher FNAIT risk among expectant mothers of different racial and ethnic characteristics, as well as the frequency of HPA-1a alloimmunization and pregnancy outcomes among these women. Subject to discussion with regulatory authorities, we expect that data from this study will contribute to a control dataset for a future single-arm Phase 3 registrational study for RLYB212. The FNAIT natural history study will also operationalize *de novo* the laboratory test paradigm for FNAIT risk and generate FNAIT laboratory test performance data that we plan to use for future regulatory discussions. As of March 1, 2024 approximately 9,400 women have been screened in the study. The Company expects screening for the natural history study to continue simultaneously with execution of the Phase 2 study.

Complement Dysregulation

We are also developing therapies that address diseases of complement dysregulation, including PNH, antiphospholipid syndrome and gMG. RLYB116 is a novel, potentially long-acting, subcutaneously injected

inhibitor of C5 in development for the treatment of patients with complement-related diseases. RLYB114 is a pegylated C5 inhibitor in development for complement-mediated ophthalmic disorders.

We have completed a Phase 1 clinical trial in healthy participants that included the study of RLYB116 as a SAD and a MAD. The SAD portion of the RLYB116 clinical trial included five cohorts with a dose ranging from 2mg up to 300mg. Data from the SAD portion of the trial showed that all study participants that were administered a single 1 mL SC injection of 100 mg of RLYB116 (n=6) demonstrated a reduction in free C5 greater than 99% within 24 hours of dosing. Subcutaneously administered RLYB116 in the SAD portion of the trial was observed to be generally well-tolerated at the 100 mg dose, with mild adverse events and no drug-related serious adverse events reported.

The MAD portion of the RLYB116 Phase 1 trial included an adaptive single-blind design with a 4-week treatment duration to evaluate the safety, tolerability, PK, and PD of RLYB116 with multiple dose SC administration. The MAD portion of the trial included 4 cohorts: Cohort 1 (weekly dosing of 100 mg), Cohort 2 (3 doses of 100 mg the first week followed by weekly dosing), Cohort 3 (150 mg weekly dosing reduced to 125 mg weekly dosing) and Cohort 4 (75 mg twice the first week followed by 100 mg twice per week) with post-treatment / study follow-up for 10 weeks. In December 2023, we reported data from the MAD portion of the trial that demonstrated a 100 mg low volume (1 mL) once-a-week dose of subcutaneously administered RLYB116 achieved sustained mean reductions in free C5 of greater than 93%, including at Day 29 with measurement prior to the last dose. The reduction from pre-treatment free C5 at 24 hours after the first dose of 100 mg was greater than 99%. RLYB116 administered in the MAD portion of the trial as a 100 mg once-a-week dose was also observed to be generally well tolerated.

Based on the MAD data and additional work we have conducted with RLYB116, we believe that RLYB116 has the potential to be an effective treatment for patients with certain complement-mediated diseases, including gMG. We have prioritized enhancements to the manufacturing process that are intended to improve tolerability at higher doses with a low injection volume and infrequent SC administration, thereby opening up the opportunity to treat a wider range of complement-mediated diseases in addition to gMG including PNH and antiphospholipid syndrome. We expect the manufacturing work to be completed in the second half of 2024.

In February 2023, we entered into a collaboration with EyePoint and are using EyePoint's proprietary technology for sustained intraocular drug delivery, with the initial focus on geographic atrophy, an advanced form of age-related macular degeneration that leads to irreversible vision loss. Rallybio and EyePoint expect to provide an update on this collaboration in the first half of 2024.

Hematological Disorders

In May 2022, we obtained worldwide exclusive rights to RLYB331, a preclinical, monoclonal antibody that is designed to inhibit MTP-2. The inhibition of MTP-2 significantly increases levels of hepcidin, decreases iron load and treats ineffective erythropoiesis. We believe RLYB331 has the potential to address a significant unmet need for patients with severe anemia with ineffective red blood cell production or erythropoiesis and iron overload, such as polycythemia vera, beta thalassemia and a subset of myelodysplastic syndromes, amongst others. Currently these patients are underserved by the existing standard of care. We are continuing with preclinical activities to support the transition of RLYB331 into clinical development and expect to report data from this program in the first half of 2024.

Metabolic Disorders

In collaboration with Exscientia, we are working toward the selection of a small molecule development candidate to advance into the clinic targeting an Ectonucleotide Pyrophosphatase/Phosphodiesterase 1 inhibitor for the treatment of patients with HPP. We and Exscientia continue to work toward the selection of a small molecule development candidate to advance into the clinic targeting ENPP1 for the treatment of patients with HPP. Proof of mechanism studies are in progress with a leading global HPP expert. We plan to provide an update on the progress of the program in the second half of 2024.

In December 2022, we entered into a strategic alliance to discover, develop, and commercialize novel antibody-based therapeutics for rare diseases. This multi-year, multi-target collaboration will combine AbCellera's antibody discovery engine with our clinical and commercial expertise in rare diseases to identify optimal clinical candidates with a goal of delivering therapies to patients. The first program is focused on addressing the significant unmet therapeutic needs of patients with rare metabolic diseases.

Our Operations

Since inception, we have devoted substantially all of our resources to raising capital, organizing and staffing the Company, business planning, conducting discovery and research activities, acquiring or discovering product candidates, establishing and protecting our intellectual property portfolio, developing and progressing our product candidates, preparing for and conducting clinical trials and establishing arrangements with third parties for the manufacture of our product candidates and component materials, including activities relating to our preclinical development and manufacturing activities for each of our programs. We do not have any product candidates approved for sale and have not generated any revenue from product sales.

Since our inception, we have funded our operations primarily through equity financings. From our inception and prior to our IPO, we received proceeds of approximately $182.5 million from equity financings. In August 2021, we closed our IPO and issued and sold 7,130,000 shares of common stock, inclusive of 930,000 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $13.00 per share. We received net proceeds of approximately $83.0 million, after deducting underwriting discounts and commissions and other offering costs.

In November 2022, we completed a follow-on offering of approximately $54.8 million pursuant to which we issued 5,803,655 shares of common stock, inclusive of 803,654 shares of common stock sold pursuant to the partial exercise of the underwriters' option to purchase additional shares at a price of $6.00 per share and to certain investors in lieu of common stock, pre-funded warrants to purchase up to an aggregate of 3,333,388 shares of common stock at a price of $5.9999, which represents the per share public offering price for the shares less the $0.0001 per share exercise price for each pre-funded warrant. The net proceeds from the November 2022 follow-on offering were approximately $50.8 million, after deducting underwriting discounts and commissions and other offering costs.

As of December 31, 2023, we had cash, cash equivalents and marketable securities of $109.9 million. We believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements into the middle of 2026. This estimate and our expectation to advance the preclinical and clinical development of RLYB212, RLYB116, and any other product candidates are based on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect, or our clinical trials may be more expensive, time consuming or difficult to design or implement than we currently anticipate. See “—Liquidity and Capital Resources.”

We have incurred significant operating losses since inception, including net losses of $74.6 million and $66.7 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $235.2 million. These losses have resulted primarily from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. We have not commercialized any products and have never generated revenue from the commercialization of any product. We expect to incur significant additional operating losses in the foreseeable future as we advance our programs through preclinical and clinical development, expand our research and development activities, acquire and develop new product candidates, complete preclinical studies and clinical trials, finance our business development strategy, seek regulatory approval for the commercialization of our product candidates and commercialize our products, if approved. Our expenses will increase substantially over time if and as we:

- advance our planned Phase 2 clinical trial for RLYB212, our lead product candidate for our FNAIT program;
- advance our FNAIT natural history study and any other studies to support our development program and related regulatory submissions for RLYB212;
- plan for and conduct any future clinical trials for RLYB116 and any of our other product candidates;
- seek regulatory approvals for RLYB212, RLYB116 and any other product candidates, as well as for any related companion diagnostic, if required;
- advance our discovery and preclinical development activities for our product candidates;
- continue to discover and develop additional product candidates;
- hire additional clinical, scientific, and commercial personnel;
- acquire or in-license other product candidates or technologies;

- maintain, expand, and protect our intellectual property portfolio;
- secure manufacturing sources and supply chain capacity sufficient to produce adequate quantities of our product candidates, including any product candidate for which we obtain regulatory approval; and
- establish a sales, marketing and distribution infrastructure to commercialize our programs, if approved, and for any other product candidates for which we may obtain marketing approval.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Our inability to raise capital as and when needed could have a negative impact on our financial condition and ability to pursue our business strategies. There can be no assurances, however, that the current operating plan will be achieved or that additional funding will be available on terms acceptable to us, or at all.

Components of Results of Operations

Operating Expenses

Research and Development Expenses

Research and development expenses consist of costs incurred in connection with our research and development activities, including our drug discovery efforts and the development of our product candidates. We expense research and development costs as incurred, which include:

- external research and development expenses incurred under agreements with third parties, such as CROs as well as investigative sites and consultants that conduct our clinical trials and other scientific development services;
- costs related to manufacturing material for our clinical trials, including expenses related to the manufacturing scale-up and fees paid to CMOs;
- employee-related expenses, including salaries, bonuses, benefits, share-based compensation and other related costs for those employees involved in research and development efforts;
- costs of outside consultants, including their fees, and related travel expenses;
- expenses to acquire technologies, such as intellectual property, to be used in research and development including in-process research and development ("IPR&D") that has no alternative future use at the time of asset acquisitions;
- costs related to compliance with quality and regulatory requirements; and
- facilities, depreciation and other indirect costs allocated to employees and activities supporting our research and development efforts.

Costs for certain activities are recognized based on an evaluation of the progress to completion of each specific contract using information and data provided to us by our vendors and analyzing the progress of our research studies or other services performed. Significant judgments and estimates are made in determining the expenses incurred balances at the end of any reporting period.

Our direct, external research and development expenses consist primarily of fees paid to outside consultants, CROs, CMOs and research laboratories in connection with our process development, manufacturing and clinical development activities. Our direct external research and development expenses also include fees incurred under license and intellectual property purchase agreements. We track these external research and development costs on a program-by-program basis.

We do not allocate employee costs, costs associated with our facilities, including depreciation or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources and third-party consultants primarily to conduct our research and development activities as well as for managing our process development, manufacturing and clinical development activities.

The successful development of our product candidates is highly uncertain. We plan to continue investing in our research and development activities for the foreseeable future as we continue the development of our product candidates and manufacturing processes and conduct discovery and research activities for our clinical

programs. We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future clinical trials of our product candidates due to the inherently unpredictable nature of preclinical and clinical development. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future clinical trials, regulatory developments, our ongoing assessments as to each product candidate's commercial potential and the availability of capital. We will need to raise substantial additional capital in the future. Our clinical development costs are expected to increase significantly as our programs advance to later stages of development. We anticipate that our expenses may fluctuate from quarter to quarter, particularly due to the numerous risks and uncertainties associated with developing product candidates, including the uncertainty of:

- the scope, rate of progress and expenses of our ongoing research activities and clinical trials and other research and development activities;
- successful enrollment in and completion of clinical trials;
- whether our product candidates show safety and efficacy in our clinical trials;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- receipt of marketing approvals from applicable regulatory authorities;
- commercializing product candidates, if and when approved, whether alone or in collaboration with others; and
- continued acceptable safety profile of the products following any regulatory approval.

Any changes in the outcome of any of these variables with respect to the development of our product candidates in clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. For example, if the FDA, EMA or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits and share-based compensation for our personnel in executive, legal, business development, finance and accounting, and other administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters, professional fees paid for accounting, auditing, tax and consulting services, insurance costs, travel expenses and direct and allocated facility costs not otherwise included in research and development expenses.

Total Other Income, Net

Total other income, net, includes interest income earned on cash, cash equivalents and marketable securities, and income and expense items.

Loss on Investment in Joint Venture

The Company recognizes its pro-rata share of losses in the joint venture with Exscientia on its consolidated statements of operations and comprehensive loss within the loss on investment in joint venture line item, with a corresponding change to the joint venture investment asset on the consolidated balance sheets for equity method investments for which it does not have a controlling interest in.

Results of Operations

Comparison of the years ended December 31, 2023 and 2022

The following table summarizes our results of operations:

(in thousands)	FOR THE YEAR ENDED DECEMBER 31, 2023	2022	CHANGE
Operating expenses:			
Research and development	$ 53,544	$ 40,689	$ 12,855
General and administrative	25,388	27,195	(1,807)
Total operating expenses	78,932	67,884	11,048
Loss from operations	(78,932)	(67,884)	(11,048)
Total other income, net	6,409	2,305	4,104
Loss before equity in losses of joint venture	(72,523)	(65,579)	(6,944)
Loss on investment in joint venture	2,041	1,075	966
Net loss	$ (74,564)	$ (66,654)	$ (7,910)

Operating Expenses

Research and Development Expenses

The following table summarizes our research and development costs for each of the periods presented:

(in thousands)	FOR THE YEAR ENDED DECEMBER 31, 2023	2022	CHANGE
Direct research and development by program			
RLYB212	$ 25,685	$ 13,151	$ 12,534
RLYB116	8,791	7,269	1,522
RLYB114	180	2,116	(1,936)
RLYB331	2,418	967	1,451
Other program candidates	813	—	813
Asset acquisition IPR&D expense	—	3,073	(3,073)
Other unallocated research and development costs			
Personnel expenses (including share-based compensation)	14,160	13,079	1,081
Other expenses	1,497	1,034	463
Total research and development expenses	$ 53,544	$ 40,689	$ 12,855

Research and development expenses were $53.5 million for the year ended December 31, 2023, compared to $40.7 million for the year ended December 31, 2022. The increase of $12.9 million was primarily due to:

- a $12.5 million increase in costs related to the development of RLYB212, primarily attributable to an increase in clinical development and manufacturing costs;
- a $1.5 million increase in costs related to the development of RLYB116, primarily attributable to an increase in clinical and other related development costs; offset by a decrease in manufacturing costs;
- a $1.5 million increase in costs related to the development of RLYB331, primarily attributable to an increase in preclinical research and development and manufacturing costs; and
- a $1.1 million increase in payroll and personnel-related expenses, including an increase of $1.1 million in non-cash share-based compensation expense.

These increases were partially offset by:

- a $3.1 million decrease in asset acquisition IPR&D expense related to the acquisition of the worldwide exclusive rights to Sanofi's KY1066, now referred to as RLYB331 in the second quarter 2022. We did not record any asset acquisition related IPR&D expense for the year ended December 31, 2023; and
- a $1.9 million decrease in costs related to the development of RLYB114, primarily attributable to a decrease in preclinical research and development and manufacturing costs as compared to the year ended December 31, 2022.

We anticipate that our research and development expenses will decline given our recent decision to prioritize our portfolio and reduce our research and development headcount.

General and Administrative Expenses

General and administrative expenses were $25.4 million for the year ended December 31, 2023, compared to $27.2 million for the year ended December 31, 2022. The decrease of $1.8 million is primarily related to a decrease in payroll and personnel-related costs and director and officer insurance premiums; offset by increases in other general and administrative related expenses.

We anticipate that our general and administrative expenses related to providing administrative support to our research and development activities will slightly decline in the future in connection with our recent decision to prioritize our development portfolio.

Total Other Income, Net

Total other income, net, for the year ended December 31, 2023 was $6.4 million compared to $2.3 million for the year ended December 31, 2022. The increase in total other income of $4.1 million is primarily attributable to an increase in interest income from marketable securities.

Loss on Investment in Joint Venture

Loss on investment in joint venture for the year ended December 31, 2023 was $2.0 million compared to $1.1 million for the year ended December 31, 2022. The increase in loss on investment in joint venture of $1.0 million is primarily attributable to an increase in REVI preclinical development costs.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have funded our operations primarily through equity financings. From our inception and prior to our IPO, we received proceeds of approximately $182.5 million from equity financings. In August 2021, we closed our IPO and issued and sold 7,130,000 shares of common stock, inclusive of 930,000 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $13.00 per share. We received net proceeds of approximately $83.0 million, after deducting underwriting discounts and commissions and other offering costs.

In August 2022, we filed a Registration Statement on Form S-3 (the "Shelf") with the SEC in relation to the registration and potential future issuance of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof in the aggregate amount of up to $300.0 million. The Shelf was declared effective on August 15, 2022. The Company also simultaneously entered into the Sales Agreement with Cowen. In accordance with the terms of the Sales Agreement, we may offer and sell shares of our common stock having an aggregate offering price of up to $100.0 million from time to time at prices through Cowen acting as our agent. Pursuant to the Sales Agreement, sales of our common stock, if any, will be made in sales deemed to be "at the market offerings" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended (the "Securities Act"). Under the Sales Agreement, Cowen will be entitled to compensation equal to 3.0% of the gross proceeds of any shares of common stock sold under the Sales Agreement. As of December 31, 2023, the Company had not sold any shares of common stock pursuant to the Sales Agreement.

In November 2022, we completed a follow-on offering of approximately $54.8 million consisting of 5,803,655 shares of common stock, inclusive of 803,654 shares of common stock sold pursuant to the partial exercise of the underwriters' option to purchase additional shares at the price of $6.00 per share, and to certain investors in lieu of common stock, pre-funded warrants to purchase up to an aggregate of 3,333,388 shares of common stock at a price of $5.9999, which represents the per share public offering price for the shares less the $0.0001 per share exercise price for each pre-funded warrant. The net proceeds from the November 2022 follow-on

offering were approximately $50.8 million, after deducting underwriting discounts and commissions and other offering costs.

As of December 31, 2023, we had $109.9 million of cash, cash equivalents and marketable securities.

Uses of Liquidity

We currently have no ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years. See "Contractual Obligations" below.

Funding Requirements

We believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements into the middle of 2026. This estimate and our expectation to advance the development of RLYB212, RLYB116, and any other product candidates are based on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect, or our clinical trials may be more expensive, time consuming or difficult to design or implement than we currently anticipate.

Management has implemented cash preservation initiatives including conducting a prioritization of its research and development activities with a primary focus on RLYB212, reviewing certain discretionary expenses and managing the timing of other development activities. However, we expect to incur significant expenses and operating losses in the foreseeable future as we advance our product candidates through clinical development, seek regulatory approval and pursue commercialization of any approved product candidates.

Because of the numerous risks and uncertainties, length of time and scope of activities associated with research, development and commercialization of pharmaceutical product candidates, we are unable to estimate the actual amount of funds we will require for development, approval and any approved marketing and commercialization activities. Our future capital requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of our clinical trials through all phases of development;
- the identification, assessment, acquisition and/or development of additional research programs and additional product candidates;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, EMA and other comparable foreign regulatory authorities, including any regulatory designations allowing for priority review and any additional clinical trials required by the FDA, EMA or other comparable foreign regulatory authorities;
- the willingness of the FDA, EMA and other comparable foreign regulatory authorities to accept our clinical trial designs, as well as data from our completed and planned preclinical studies and clinical trials, as the basis for review and approval of RLYB212, RLYB116 and any other product candidates;
- the cost and timing of the manufacture and supply of non-clinical and clinical trial material for RLYB212, RLYB116 and our other product candidates;
- the progress, timing and costs of the development by us or third parties of companion diagnostics, if required, for RLYB212 or any other product candidates, including design, manufacturing and regulatory approval;
- the cost of filing, prosecuting and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us;
- the costs associated with potential clinical trial liability or product liability claims, including the costs associated with obtaining insurance against such claims and with defending against such claims;
- the effect of competing technological and market developments;
- the cost of making royalty, milestone or other payments under our current or any future in-license agreements;

- our ability to maintain our collaborations with Exscientia and AbCellera on favorable terms and establish new collaborations;
- the extent to which we in-license or acquire additional product candidates or technologies; and
- the costs of operating as a public company.

A change in the outcome of any of these, or other variables with respect to the development of any of our product candidates, could significantly change the costs and timing associated with the development of that product candidate. We will need to continue to rely on additional financing to achieve our business objectives.

In addition to the variables described above, if and when any of our product candidates successfully complete development, we will incur substantial additional costs associated with regulatory filings, marketing approvals, post-marketing requirements, maintaining our intellectual property rights and regulatory protection, in addition to other commercial costs. We cannot reasonably estimate these costs at this time.

Until such time, if ever, as we generate significant revenue from product sales, we expect to finance our operations through the sale of equity, debt financings, marketing and distribution arrangements and collaborations, strategic alliances and licensing arrangements or other sources. We currently have no credit facility or committed sources of capital. Any future sales of equity will result in dilution to our existing stockholders. If we raise additional funds through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and we may need to dedicate a substantial additional portion of any operating cash flows to the payment of principal and interest on such indebtedness. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, intellectual property, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate product candidate development or future commercialization efforts.

Cash Flows

The following table summarizes our cash flows for each of the periods presented:

	FOR THE YEAR ENDED DECEMBER 31,	
(in thousands)	**2023**	**2022**
Net cash used in operating activities	$ (60,265)	$ (57,284)
Net cash provided by (used in) investing activities	27,658	(112,170)
Net cash provided by (used in) financing activities	143	51,078
Net decrease in cash and cash equivalents	$ (32,464)	$ (118,376)

Operating Activities

During the year ended December 31, 2023, net cash used in operating activities was $60.3 million as compared to $57.3 million for the year ended December 31, 2022. The increase in cash used in operating activities was primarily due to an increase in research and development expenses. Our research and development expenses increased primarily due to the advancement of our RLYB212 and RLYB116 product candidates, the advancement of RLYB331 and an increase in payroll and personnel-related costs. These research and development expenses were offset by a decrease in expenses related to IPR&D expenses associated with the acquisition of worldwide exclusive rights to Sanofi's KY1066, now referred to as RLYB331 and research and development expenses related to the development of RLYB114 as compared to the year ended December 31, 2022.

Investing Activities

Net cash provided by investing activities was $27.7 million for the year ended December 31, 2023 as compared to $112.2 million of net cash used in investing actives for the year ended December 31, 2022. The increase in net cash provided by investing activities was primarily related to the proceeds from maturities of highly rated debt securities during the year ended December 31, 2023 as compared to the purchases of highly rated debt securities during the year ended December 31, 2022.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2023 was $0.1 million, representing the issuance of common stock under the 2021 Employee Stock Purchase Plan, offset by payments of offering costs related to our November 2022 follow-on offering. Net cash provided by financing activities for the year ended December 31, 2022 was $51.1 million, primarily representing the net proceeds from our November 2022 follow-on offering, after deducting underwriting discounts and commissions and payments of other offering costs.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2023:

	PAYMENTS DUE BY PERIOD				
(in thousands)	TOTAL	LESS THAN 1 YEAR	1-3 YEARS	3-5 YEARS	MORE THAN 5 YEARS
Operating lease obligations	$ 406	$ 230	$ 176	$ —	$ —

The contractual obligation amounts in the table above are associated with contracts that are enforceable and legally binding and that specify all significant terms, including fixed or minimum services to be used, fixed, minimum or variable price provisions and the approximate timing of the actions under the contracts.

Purchase and Other Obligations

We enter contracts in the normal course of business with CROs and other third-party vendors for clinical trials and testing and manufacturing services. Aside from those included in the table above, most contracts do not contain minimum purchase commitments and are cancellable by us upon written notice. Payments that may be due upon cancellation consist of payments for services provided or expenses incurred. These payments are not included in the table above as the amount and timing of such payments are not known.

We may incur contingent payments upon our achievement of clinical, regulatory and commercial milestones, as applicable under agreements we have entered into with various third-party entities pursuant to which we have acquired or in-licensed intellectual property. Due to the uncertainty of the achievement and timing of the events that require payment under these agreements, the amounts to be paid by us are not fixed or determinable at this time and have not been included in the table above. See “Business—License Agreements” and “Business—Asset Purchase Agreements” included elsewhere in this Annual Report on Form 10-K for a description of these agreements.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 “Summary of Significant Accounting Policies Basis of Presentation and Principles of Consolidation” to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our research and development expenses that are incurred as of each reporting period. This process involves reviewing open contracts and purchase orders, communicating with our personnel and with vendors 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

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.

We base our expenses related to research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on our behalf. The financial terms of these agreements are 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 vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid balance accordingly. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period.

Share-Based Compensation

The Company accounts for share-based compensation in accordance with ASC 718, *Compensation—Stock Compensation*. Generally, share-based compensation is measured at the grant date for all equity-based awards made to employees based on the fair value of the awards and is recognized over the requisite service period, which is generally the vesting period. Share-based compensation for awards with performance conditions are recognized over the service period when achievement of the performance condition is probable. The Company has elected to recognize the actual forfeitures by reducing the share-based compensation in the same period as the forfeitures occur. The Company classifies share-based compensation in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipients' payroll costs are classified.

The Black-Scholes option-pricing model uses as inputs the fair value of our common stock and assumptions we make for the volatility of our common stock, the expected term of our common stock options, the risk-free interest rate for a period that approximates the expected term of our common stock options, and our expected dividend yield. See Note 2 "Summary of Significant Accounting Policies Basis of Presentation and Principles of Consolidation" of our consolidated financial statements for additional information on the assumptions utilized in the Black-Scholes option-pricing model.

Emerging Growth Company and Smaller Reporting Company

As an emerging growth company (an "EGC") under the JOBS Act, we may delay the adoption of certain accounting standards until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act, for EGCs include presentation of only two years of audited financial statements in a registration statement for an initial public offering, an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation, and less extensive disclosure about our executive compensation arrangements. Additionally, the JOBS Act provides that an EGC can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an EGC to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an EGC. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies. Therefore, the reported results of operations contained in our consolidated financial statements may not be directly comparable to those of other public companies.

We are also a "smaller reporting company" meaning that the market value of our stock held by non-affiliates is less than $700.0 million and our annual revenue was less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue was less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less

than $700.0 million. If we are a smaller reporting company at the time we cease to be an EGC, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Off-Balance Sheet Arrangements

As of December 31, 2023 and 2022, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 “Summary of Significant Accounting Policies Basis of Presentation and Principles of Consolidation” to our consolidated financial statements for the year ended December 31, 2023 appearing elsewhere in this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act, and are not required to provide the information under this item.

Item 8. Financial Statements and Supplementary Data.

The financial information required by Item 8 is located beginning on page F-1 of this Annual Report.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures.

Our management, with the participation of our chief executive officer and chief financial officer (our principal executive officer and principal financial and accounting officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2023. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company on the reports that it files or submits under the Exchange Act is accumulated and communicated to management, including, our principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgement in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2023, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Internal Control Over Financial Reporting

Management's Annual Report on Internal Control over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Our management, under the supervision and with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2023 based on the criteria in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework). Based on the results of its evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2023.

Internal control over financial reporting includes policies and procedures that: (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and disposition of assets; (2) provide

reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that receipts and expenditures are being made only in accordance with the authorization of its management and directors; and (3) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on its financial statements. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting.
There has been no change in our internal control over financial reporting as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act during our most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.
None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.
Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.
The information required by this Item 10 will be included in our Definitive Proxy Statement to be filed with the Securities Exchange Commission with respect to our 2024 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 11. Executive Compensation.
The information required by this Item 11 will be included in our Definitive Proxy Statement to be filed with the Securities Exchange Commission with respect to our 2024 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.
The information required by this Item 12 will be included in our Definitive Proxy Statement to be filed with the Securities Exchange Commission with respect to our 2024 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.
The information required by this Item 13 will be included in our Definitive Proxy Statement to be filed with the Securities Exchange Commission with respect to our 2024 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.
The information required by this Item 14 will be included in our Definitive Proxy Statement to be filed with the Securities Exchange Commission with respect to our 2024 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1) For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page F-1 of this Annual Report on Form 10-K, incorporated into this Item by reference.

(2) Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

(3) Exhibits:

Exhibit Number	Description
2.1	Form of Plan of Liquidation and Dissolution (incorporated by reference to Exhibit 2.1 to the Company's Registration Statement on Form S-1 (File No. 333-257655), as amended, filed with the SEC on July 22, 2021).
3.1	Amended and Restated Certificate of Incorporation of Rallybio Corporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-40693), filed with the SEC on August 2, 2021).
3.2	Amended and Restated Bylaws of Rallybio Corporation (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-40693), filed with the SEC on August 2, 2021).
4.1	Specimen stock certificate evidencing shares of common stock (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 (File No. 333-257655), as amended, filed with the SEC on July 22, 2021).
4.2	Registration Rights Agreement, dated July 28, 2021, among the Registrant and certain of its stockholders (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 001-40693), filed with the SEC on August 2, 2021).
4.3	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 001-40693), filed with the SEC on November 14, 2022)
4.4	Description of Registrant's Securities.
10.1+	Asset Purchase Agreement, by and between Rallybio IPA, LLC and Prophylix AS, dated June 28, 2019 (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 (File No. 333-257655), filed with the SEC on July 2, 2021).
10.2+	Asset Transfer Agreement, by and between Swedish Orphan Biovitrum AB (PUBL) and IPC Research, LLC, dated March 15, 2019 (incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1 (File No. 333-257655), filed with the SEC on July 2, 2021).
10.3+	Product License Agreement, by and between Affibody AB and Swedish Orphan Biovitrum AB (PUBL), dated March 9, 2012, and assigned to IPC Research, LLC on March 15, 2019 (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1 (File No. 333-257655), filed with the SEC on July 2, 2021).
10.4+	Amendment No. 1 to Product License Agreement, by and between Affibody AB and Swedish Orphan Biovitrum AB (PUBL), dated January 1, 2018, and assigned to IPC Research, LLC on March 15, 2019 (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1 (File No. 333-257655), filed with the SEC on July 2, 2021).
10.5+	Amendment No. 2 to Product License Agreement, by and between Affibody AB and IPC Research, LLC, dated December 22, 2020 (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 (File No. 333-257655), filed with the SEC on July 2, 2021).
10.6+	License Agreement, by and between Rallybio IPE, LLC and Kymab Limited, dated as of May 5, 2022 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-40693), filed with the SEC on August 8, 2022).
10.7+	Operating Agreement of RE Ventures I, LLC, by and between Rallybio IPB, LLC and Exscientia Limited, dated July 19, 2019 (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1 (File No. 333-257655), filed with the SEC on July 2, 2021).
10.8#	Form of Indemnification Agreement, between the Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1 (File No. 333-257655), as amended, filed with the SEC on July 22, 2021).
10.13#	Rallybio Corporation 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.12 to the Company's Registration Statement on Form S-1 (File No. 333-257655), as amended, filed with the SEC on July 22, 2021).
10.14#	Form of Non-Qualified Stock Option Award Agreement under the Rallybio Corporation 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1 (File No. 333-257655), as amended, filed with the SEC on July 22, 2021).
10.15#	Non-Qualified Stock Option Award Agreement for Non-Employee Directors under the Rallybio Corporation 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1 (File No. 333-257655), as amended, filed with the SEC on July 22, 2021).

10.16#	Form of Incentive Stock Option Award Agreement under the Rallybio Corporation 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1 (File No. 333-257655), as amended, filed with the SEC on July 22, 2021).
10.17#	Form of Restricted Stock Unit Award Agreement under the Rallybio Corporation 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1 (File No. 333-257655), as amended, filed with the SEC on July 22, 2021).
10.18#	Form of Restricted Stock Unit Award Agreement for Non-Employee Directors under the Rallybio Corporation 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.17 to the Company's Registration Statement on Form S-1 (File No. 333-257655), as amended, filed with the SEC on July 22, 2021).
10.19#	Rallybio Corporation 2021 Cash Incentive Plan (incorporated by reference to Exhibit 10.18 to the Company's Registration Statement on Form S-1 (File No. 333-257655), as amended, filed with the SEC on July 22, 2021).
10.20#	Rallybio Corporation 2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.19 to the Company's Registration Statement on Form S-1 (File No. 333-257655), as amended, filed with the SEC on July 22, 2021).
10.21#	Second Amended and Restated Employment Agreement, by and between Rallybio, LLC, Rallybio Corporation and Stephen Uden, dated August 1, 2023 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-40693), filed with the SEC on August 8, 2023).
10.22#	Second Amended and Restated Employment Agreement, by and between Rallybio, LLC, Rallybio Corporation and Martin Mackay, dated August 1, 2023 (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q (File No. 001-40693), filed with the SEC on August 8, 2023).
10.23#	Amended and Restated Employment Agreement between Rallybio, LLC and Jeffrey M. Fryer (incorporated by reference to Exhibit 10.22 to the Company's Registration Statement on Form S-1 (File No. 333-257655), as amended, filed with the SEC on July 22, 2021).
10.24#	Employment Agreement between Rallybio Corporation and Jonathan I. Lieber, dated as of February 1, 2023 (incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K (File No. 001-40693), filed with the SEC on March 6, 2023).
10.25#	Confidential Release and Separation Agreement between Rallybio Corporation and Jeffrey M. Fryer, dated as of February 15, 2023 (incorporated by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K (File No. 001-40693), filed with the SEC on March 6, 2023).
10.26#	Form of Equity Adjusted Notice (incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-1 (File No. 333-257655), as amended, filed with the SEC on July 22, 2021).
21.1*	Subsidiaries of Registrant.
23.1*	Consent of Deloitte & Touche LLP, independent registered public accounting firm.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97*	Policy Relating to Recovery of Erroneously Awarded Compensation
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document

101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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* Filed herewith.

\# Indicates management contract or compensatory plan

\+ Portions of this exhibit (indicated by asterisks) have been redacted because they are both not material and the registrant customarily and actually treats such information as private or confidential.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

RALLYBIO CORPORATION

Date: March 12, 2024

By: /s/ Stephen Uden

Stephen Uden, M.D.

Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ Stephen Uden **Stephen Uden, M.D.**	Chief Executive Officer, President and Director (Principal Executive Officer)	March 12, 2024
/s/ Jonathan I. Lieber **Jonathan I. Lieber**	Chief Financial Officer and Treasurer (Principal Accounting and Financial Officer)	March 12, 2024
/s/ Martin W. Mackay **Martin W. Mackay, Ph.D.**	Executive Chairman	March 12, 2024
/s/ Helen M. Boudreau **Helen M. Boudreau**	Director	March 12, 2024
/s/ Wendy K. Chung **Wendy K Chung, M.D., Ph.D.**	Director	March 12, 2024
/s/ Rob Hopfner **Rob Hopfner, R.Ph., Ph.D., MBA**	Director	March 12, 2024
/s/ Ronald M. Hunt **Ronald M. Hunt**	Director	March 12, 2024
/s/ Lucian Iancovici **Lucian Iancovici, M.D.**	Director	March 12, 2024
/s/ Hui Liu **Hui Liu, Ph.D.**	Director	March 12, 2024
/s/ Christine A. Nash **Christine A. Nash, MBA**	Director	March 12, 2024
/s/ Kush M. Parmar **Kush M. Parmar, M.D., Ph.D.**	Director	March 12, 2024
/s/ Paula Soteropoulos **Paula Soteropoulos**	Director	March 12, 2024

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Rallybio Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Rallybio Corporation and subsidiaries (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows, for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting 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.

/s/ Deloitte & Touche LLP

Hartford, Connecticut
March 12, 2024

We have served as the Company's auditor since 2018.

RALLYBIO CORPORATION

Consolidated Balance Sheets

(in thousands, except share and per share amounts)	DECEMBER 31, 2023	DECEMBER 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 24,494	$ 56,958
Marketable securities	85,435	112,036
Prepaid expenses and other assets	4,860	10,502
Total current assets	114,789	179,496
Property and equipment, net	246	385
Operating lease right-of-use assets	346	524
Investment in joint venture	239	30
Total assets	$ 115,620	$ 180,435
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 976	$ 1,114
Accrued expenses	8,068	9,449
Operating lease liabilities	219	181
Total current liabilities	9,263	10,744
Operating lease liabilities, noncurrent	173	374
Total liabilities	9,436	11,118
Commitments and contingencies (Note 10)		
Stockholders' equity		
Common stock, $ 0.0001 par value per share; 200,000,000 shares authorized as of December 31, 2023 and 2022, respectively; and 37,829,565 and 37,837,369 shares issued and outstanding as of December 31, 2023 and 2022, respectively	4	4
Preferred stock, $ 0.0001 par value per share; 50,000,000 shares authorized as of December 31, 2023 and 2022, respectively; no shares issued or outstanding as of December 31, 2023 and 2022, respectively	—	—
Additional paid-in capital	341,410	330,208
Accumulated other comprehensive gain (loss)	15	(214)
Accumulated deficit	(235,245)	(160,681)
Total stockholders' equity	106,184	169,317
Total liabilities and stockholders' equity	$ 115,620	$ 180,435

See accompanying notes of the consolidated financial statements

RALLYBIO CORPORATION

Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share amounts)	FOR THE YEAR ENDED DECEMBER 31, 2023	2022
Operating expenses:		
Research and development	$ 53,544	$ 40,689
General and administrative	25,388	27,195
Total operating expenses	78,932	67,884
Loss from operations	(78,932)	(67,884)
Other income:		
Interest income	6,147	1,963
Other income	262	342
Total other income, net	6,409	2,305
Loss before equity in losses of joint venture	(72,523)	(65,579)
Loss on investment in joint venture	2,041	1,075
Net loss	$ (74,564)	$ (66,654)
Net loss per common share, basic and diluted	$ (1.84)	$ (2.09)
Weighted-average common shares outstanding, basic and diluted	40,447,388	31,821,311
Other comprehensive gain (loss):		
Net unrealized gain (loss) on marketable securities	229	(214)
Other comprehensive gain (loss)	229	(214)
Comprehensive loss	$ (74,335)	$ (66,868)

See accompanying notes of the consolidated financial statements

RALLYBIO CORPORATION

Consolidated Statements of Changes in Stockholders' Equity

(in thousands, except share amounts)	COMMON SHARES	COMMON AMOUNT	ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE GAIN (LOSS)	STOCKHOLDERS' EQUITY
December 31, 2021	32,129,970	$ 3	$ 269,626	$ (94,027)	$ —	$ 175,602
Issuance of common stock and pre-funded warrants upon completion of the follow-on offering, net of underwriting discounts and commissions and offering costs of $ 3,976	5,803,655	1	50,845	—	—	50,846
Issuance of common stock from the stock purchase plan	38,845	—	217	—	—	217
Issuance of common stock from the stock award plan	2,000	—	—	—	—	—
Issuance of common stock from exercise of stock options	2,014	—	21	—	—	21
Forfeiture of restricted common stock	(139,115)	—	—	—	—	—
Share-based compensation expense	—	—	9,499	—	—	9,499
Net loss	—	—	—	(66,654)	—	(66,654)
Other comprehensive gain (loss)	—	—	—	—	(214)	(214)
Balance, December 31, 2022	37,837,369	$ 4	$ 330,208	$ (160,681)	$ (214)	$ 169,317
Issuance of common stock from the stock purchase plan	79,283	$ —	$ 282	$ —	$ —	$ 282
Issuance of common stock from the stock award plan	11,219	—	—	—	—	—
Forfeiture of restricted common stock	(98,306)	—	—	—	—	—
Share-based compensation expense	—	—	10,920	—	—	10,920
Net loss	—	—	—	(74,564)	—	(74,564)
Other comprehensive gain (loss)	—	—	—	—	229	229
Balance, December 31, 2023	37,829,565	$ 4	$ 341,410	$ (235,245)	$ 15	$ 106,184

See accompanying notes of the consolidated financial statements

RALLYBIO CORPORATION

Consolidated Statements of Cash Flows

(in thousands)	FOR THE YEAR ENDED DECEMBER 31, 2023	2022
Cash Flows Used in Operating Activities:		
Net loss	$ (74,564)	$ (66,654)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	150	167
Net accretion of discounts/premiums on debt securities	(3,089)	(435)
Stock-based compensation	10,920	9,499
Loss on investment in joint venture	2,041	1,075
Changes in operating assets and liabilities:		
Prepaid expenses, right-of-use assets and other assets	5,819	(4,645)
Accounts payable	(99)	487
Accrued expenses and operating lease liabilities	(1,443)	3,222
Net cash used in operating activities	$ (60,265)	$ (57,284)
Cash Flows Provided by (Used in) Investing Activities:		
Purchases of marketable securities	(108,414)	(201,316)
Proceeds from maturities of marketable securities	138,334	89,500
Purchase of property and equipment	(12)	(54)
Investment in joint venture	(2,250)	(300)
Net cash provided by (used in) investing activities	$ 27,658	$ (112,170)
Cash Flows Provided by (Used in) Financing Activities:		
Proceeds from the issuance of common stock and pre-funded warrants upon the completion of the follow-on offering, net of underwriting discounts and commissions of $ 3,289	—	51,533
Proceeds from the issuance of common stock from the stock purchase plan	282	217
Proceeds from the issuance of common stock from exercise of stock options	—	21
Payments of offering costs	(139)	(693)
Net cash provided by (used in) financing activities	$ 143	$ 51,078
Net decrease in cash and cash equivalents	(32,464)	(118,376)
Cash and cash equivalents—beginning of year	56,958	175,334
Cash and cash equivalents—end of year	$ 24,494	$ 56,958
Supplemental Disclosures of Noncash Investing and Financing Activities:		
Offering costs in accounts payable and accrued expenses	$ —	$ 139

See accompanying notes of the consolidated financial statements

RALLYBIO CORPORATION

Notes to Consolidated Financial Statements

1. BUSINESS

Rallybio Corporation and subsidiaries ("Rallybio", the "Company", "we", "our", or "us") is a clinical-stage biotechnology company comprised of experienced biopharma industry leaders with extensive research, development, and rare disease expertise with a mission to develop and commercialize life-transforming therapies for patients with severe and rare diseases. Since our launch in January 2018, we have built a broad pipeline of promising product candidates aimed at addressing diseases with unmet medical need in the areas of maternal fetal health, complement dysregulation, hematology, and metabolic disorders. Our two most advanced programs are in clinical development: RLYB212, an anti-HPA-1a antibody for the prevention of fetal and neonatal alloimmune thrombocytopenia (“FNAIT”) and RLYB116, an inhibitor of complement component 5 (“C5”), with the potential to treat several diseases of complement dysregulation. Both programs have completed Phase 1 clinical trials, and we currently plan to initiate a Phase 2 clinical trial of RLYB212 in the second half of 2024.

In August 2021, the Company completed its initial public offering ("IPO"), pursuant to which it issued and sold 7,130,000 shares of the Company’s common stock, inclusive of 930,000 shares sold pursuant to the full exercise of the underwriters’ option to purchase additional shares, at a public offering price of $ 13.00 per share. The gross proceeds from the IPO, including the exercise of the underwriter's option to purchase additional shares were $ 92.7 million and the net proceeds were approximately $ 83.0 million, after deducting underwriting discounts and commissions and other offering costs.

In November 2022, the Company completed a follow-on offering of approximately $ 54.8 million consisting of 5,803,655 shares of common stock, inclusive of 803,654 shares of common stock sold pursuant to the partial exercise of the underwriters' option to purchase additional shares at the price of $ 6.00 per share and to certain investors in lieu of common stock, pre-funded warrants to purchase up to an aggregate of 3,333,388 shares of common stock at a price of $ 5.9999 , which represents the per share public offering price for the shares less the $ 0.0001 per share exercise price for each pre-funded warrant. The net proceeds from the November 2022 follow-on offering were approximately $ 50.8 million, after deducting underwriting discounts and commissions and other offering costs.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES BASIS OF PRESENTATION AND PRINCIPLES OF CONSOLIDATION

Basis of Presentation— The accompanying consolidated financial statements have been prepared with accounting principles generally accepted in the United States of America (“GAAP”), and pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (“ASU”) promulgated by the Financial Accounting Standards Board (“FASB”).

Principles of Consolidation— The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates —The preparation of the Company’s consolidated financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts and disclosures in the consolidated financial statements. While management believes that estimates and assumptions used in the preparation of the consolidated financial statements are appropriate, actual results could differ from those estimates. The most significant estimates are those used in the determination of the fair value of its common units and incentive units awarded to employees prior to the Company's IPO, for purposes of recording stock-based incentive compensation, the fair value of stock options, as well as contracted research and development expenses incurred.

Liquidity and Ability to Continue as a Going Concern —The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. Management has evaluated whether there are conditions and events that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date the financial statements are issued. Since its inception, the Company has incurred net losses and negative cash flows from operations.

During the years ended December 31, 2023 and 2022, the Company incurred a net loss of $ 74.6 million and $ 66.7 million, respectively. In addition, as of December 31, 2023, the Company had an accumulated deficit of

$ 235.2 million. The Company expects to continue to generate operating losses and negative cash flows in the foreseeable future.

The Company currently expects that cash, cash equivalents and marketable securities of $ 109.9 million at December 31, 2023 will be sufficient to fund its operating expenses and capital requirements for more than 12 months from the date the consolidated financial statements are issued. However, we do not anticipate that the current cash, cash equivalents and marketable securities as of December 31, 2023 will be sufficient for us to fund any of our product candidates through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of our product candidates, if approved. We may satisfy our future cash needs through the sale of equity securities, debt financings, working capital lines of credit, corporate collaborations or license agreements, grant funding, interest income earned on invested cash balances or a combination of one or more of these sources.

Collaboration Arrangements—The Company considers the nature and contractual terms of an arrangement to assess whether an arrangement involves a joint operating activity that expose two or more parties to significant risks and rewards dependent on the commercial success of the activity. If the Company is an active participant and is exposed to significant risks and rewards dependent on the commercial success of the activity, the Company accounts for such arrangement as a collaborative arrangement under ASC 808, *Collaborative Arrangements* ("ASC 808"). ASC 808 describes arrangements within its scope and considerations surrounding presentation and disclosure, with recognition matters subjected to other authoritative guidance, in certain cases by analogy.

For arrangements determined to be within the scope of ASC 808 for certain research and development activities where a collaborative partner is not a customer following the guidance of ASC 606, *Revenue Recognition* ("ASC 606"), the Company accounts for payments due to a collaboration partner as research and development expense and for payments owed to us from our collaboration partner for the reimbursement of research and development costs as a contra-expense in the period such expenses are incurred. The Company classifies payments owed or receivables recorded as other current liabilities and other current assets, respectively, in the Company's consolidated balance sheets. See Note 3, "License and Collaboration Agreements" for additional details.

Asset Acquisitions— The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If this screen criteria is met, the transaction is accounted for as an asset acquisition. If not, further determination is required as to whether or not the Company has acquired inputs and processes that have the ability to create outputs, which would meet the definition of a business. The Company measures and recognizes asset acquisitions that are not deemed to be business combinations based on the cost to acquire the assets, which includes transaction costs. In an asset acquisition, the cost allocated to acquire in-process research and development ("IPR&D") with no alternative future use is charged to research and development expense at the acquisition date. See Note 3, "License and Collaboration Agreements" for additional details.

Variable Interest Entity—The Company evaluates its ownership, contractual, and other interests in entities to determine if it has any variable interest in a variable interest entity ("VIE"). These evaluations are complex, involve judgment, and the use of estimates and assumptions based on available historical information, among other factors. If the Company determines that an entity in which it holds a contractual, or ownership, interest is a VIE and that the Company is the primary beneficiary, the Company consolidates such entity in its consolidated financial statements. The primary beneficiary of a VIE is the party that meets both of the following criteria: (i) has the power to make decisions that most significantly affect the economic performance of the VIE; and (ii) has the obligation to absorb losses or the right to receive benefits that in either case could potentially be significant to the VIE. Management performs ongoing reassessments of whether changes in the facts and circumstances regarding the Company's involvement with a VIE will cause the consolidation conclusion to change. Changes in consolidation status are applied prospectively. The Company evaluated its investment in RE Ventures I, LLC, a limited liability company ("REV-I"), defined in Note 9, and concluded that it represented a VIE and was not deemed the primary beneficiary. If the Company is not deemed to be the primary beneficiary in a VIE, the Company accounts for the investment or other variable interests in a VIE in accordance with the applicable GAAP. See Note 9, "Investment in Joint Venture" for additional details.

Equity Method Investments—The Company accounts for investments for which it does not have a controlling interest in accordance with ASC 323, *Investments – Equity Method and Joint Ventures* ("ASC 323"). The

Company recognizes its pro-rata share of income and losses in “loss on investment in joint venture” on the consolidated statements of operations and comprehensive loss, with a corresponding change to the investment in joint venture asset on the consolidated balance sheets.

Financial Instruments—The Company’s principal financial instruments are comprised of cash, cash equivalents, available for sale marketable securities, accounts payable and accrued liabilities. The carrying value of all financial instruments approximates fair value.

Concentrations of Credit Risk— Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company invests its excess cash in money market funds and marketable securities in government insured financial institutions that are subject to minimal credit and market risk. Management believes that the Company is not exposed to significant credit risk as the Company’s deposits are held at financial institutions that management believes to be of high credit quality, and the Company has not experienced any losses on these deposits.

Cash and Cash Equivalents—The Company classifies amounts on deposit in banks and cash invested temporarily in various instruments, primarily money market funds, with original maturities of three months or less at the time of purchase as cash and cash equivalents. The carrying amounts reported in the consolidated balance sheets represent the fair values of cash and cash equivalents.

Marketable Securities — We invest our excess cash balances in highly rated United States ("U.S.") government-backed debt securities and treasuries. We classify our marketable securities as available-for-sale and accordingly, record such securities at fair value. Debt securities with original maturities of greater than 90 days are classified as available-for-sale marketable securities and debt securities with original maturities of less than 90 days from the date of purchase are classified as cash equivalents.

Unrealized gains and losses on our marketable debt securities that are deemed temporary are included in accumulated other comprehensive income (loss) as a separate component of stockholders’ equity. If any adjustment to fair value reflects a significant decline in the value of the security, we evaluate the extent to which the decline is determined to be other-than-temporary and would mark the security to market through a charge to our consolidated statements of operations and comprehensive loss. Credit losses are identified when we do not expect to receive cash flows sufficient to recover the amortized cost basis of a security. In the event of a credit loss, only the amount associated with the credit loss is recognized in operating results, with the amount of loss relating to other factors recorded in accumulated other comprehensive income (loss).

Property and Equipment—Property and equipment are recorded at cost and consist of computer and other equipment, capitalized software, furniture and fixtures and leasehold improvements. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, or for leasehold improvements, over the remaining term of the lease, if shorter. The estimated useful life for each major asset classification are as follows:

Asset Classification	Estimated Useful Life
Computer and other equipment	3 years
Capitalized software	3 years
Furniture and fixtures	6 years
Leasehold improvements	lesser of lease life or useful life

Maintenance and repairs which do not extend the lives of the assets are charged directly to expense as incurred. Upon retirement or disposal, cost and related accumulated depreciation are removed from the related accounts, and any resulting gain or loss is recognized as a component of income or loss in the consolidated statements of operations and comprehensive loss.

Impairment of Long-Lived Assets —When indications of potential impairments are present, the Company evaluates the carrying value of long-lived assets. The Company adjusts the carrying value of the long-lived assets if the sum of undiscounted expected future cash flows is less than the carrying value. No such impairments were recorded during the years ended December 31, 2023 or 2022.

Leases —At the inception of an arrangement, we determine if an arrangement is, or contains, a lease based on the facts and circumstances present in that arrangement. Lease classification, recognition, and measurement are then determined at the lease commencement date. For arrangements that contain a lease we (i) identify lease and non-lease components, (ii) determine the consideration in the contract, (iii) determine whether the

lease is an operating or financing lease; and iv) recognize lease right-of-use ("ROU") assets and liabilities. Lease liabilities and their corresponding ROU assets are recorded based on the present value of fixed, or in substance fixed, lease payments over the expected lease term. When the interest rate implicit in lease contracts is not readily determinable we use our incremental borrowing rate based on the information available at the lease commencement date, which represents an internally developed rate that would be incurred to borrow, on a collateralized basis, over a similar term, an amount equal to the lease payments in a similar economic environment.

We have elected to combine lease components with non-lease components on our office real estate asset class. Fixed, or in substance fixed, lease payments on operating leases are recognized over the expected term of the lease on a straight-line basis. Variable lease expenses that are not considered fixed, or in substance fixed, are recognized as incurred. Fixed and variable lease expense on operating leases is recognized within operating expenses within our consolidated statements of operations and comprehensive loss. Some leases include options to extend or terminate the lease and the Company includes these options in the recognition of the Company's ROU assets and lease liabilities when it is reasonably certain that the Company will exercise such options. We have elected the short-term lease exemption and, therefore, do not recognize a ROU asset or corresponding liability for lease arrangements with an original term of 12 months or less.

Income Taxes —The Company uses the asset and liability method of accounting for income taxes, as set forth in ASC 740, *Accounting for Income Taxes* ("ASC 740"). Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequence of temporary differences between the carrying amounts and the tax basis of assets and liabilities and net operating loss carry forwards, all calculated using presently enacted tax rates. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company evaluates whether deferred tax assets are more likely than not of being realized in determining whether a valuation allowance is necessary. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies. As of December 31, 2023 and 2022, the Company determined that it is more likely than not that deferred taxes will not be realized and as a result recorded a valuation allowance against its deferred tax assets. The Company files a consolidated U.S. federal income tax return and has elected to include all subsidiaries owned more than 80 %.

Research and Development Expenses —Research and development expenses are comprised of costs incurred in performing research and development activities including personnel salaries, benefits, and equity-based compensation; external research and development expenses incurred under arrangements with third parties, such as contract research organization agreements, investigational sites, and consultants; the cost of developing and manufacturing clinical study materials, program regulatory costs, expenses associated with obligations under asset acquisitions, license agreements and other direct and indirect costs. Costs incurred in connection with research and development activities are expensed as incurred. Costs are considered incurred based on an evaluation of the progress to completion of each contract using information and data provided by the respective vendors, including the Company's clinical sites. Depending upon the timing of invoicing by the service providers, the Company recognizes prepaid expenses or accrued expenses related to these costs. These prepaid expenses or accrued expenses are based on management's estimates of the work performed under service agreements, milestones achieved, and experience with similar contracts. The Company monitors each of these factors and adjusts estimates accordingly.

Deferred Offering Costs— The Company capitalizes incremental legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such equity financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity as a reduction of additional paid-in-capital generated as a result of the offering. Should the planned equity financing no longer be considered probable of being consummated, the offering costs are expensed immediately as a charge to operating expense. Deferred offering costs are included in prepaid expenses and other assets on the consolidated balance sheets. Deferred offering costs as of December 31, 2022 were $ 0.1 million. There were no deferred offering costs as of December 31, 2023.

Stock Warrants — The Company accounts for stock warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance included in ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480") and ASC 815, *Derivatives and Hedging* ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, whether the warrants meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent

quarterly period end date while the warrants are outstanding. Warrants that meet all of the criteria for equity classification are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance and remeasured each balance sheet date thereafter.

Share-Based Compensation—The Company accounts for share-based compensation in accordance with ASC 718, *Compensation—Stock Compensation* ("ASC 718"). Generally, share-based compensation is measured at the grant date for all equity-based awards made to employees based on the fair value of the awards and is recognized over the requisite service period, which is generally the vesting period. Share-based compensation for awards with performance conditions are recognized over the service period when achievement of the performance condition is probable. The Company has elected to recognize the actual forfeitures by reducing the share-based compensation in the same period as the forfeitures occur. The Company classifies share-based compensation in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipients' payroll costs are classified.

The Company estimates the fair value of options granted using the Black-Scholes option pricing model ("Black-Scholes") for stock option grants. The fair value of the Company's common stock is used to determine the fair value of restricted stock awards. Black-Scholes requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the award, the risk-free interest rate and expected dividends. Due to the lack of a public market for the Company's common stock and lack of company-specific historical and implied volatility data, the Company has based its computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to the Company. The historical volatility is calculated based on a period of time corresponding with expected term assumption. The Company uses the simplified method to calculate the expected term for options granted where the expected term equals the arithmetic average of the vesting term and the original contractual term of the options due to its lack of sufficient historical data. The risk-free interest rate is based on U.S. Treasury securities with a maturity date corresponding with the expected term of the associated award. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock.

Fair Value Measurements—ASC Topic 820, *Fair Value Measurement* ("ASC 820"), establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the assets or liabilities and are developed based on the best information available in the circumstances. ASC 820 identifies fair value as the price that would be received to sell an asset or paid to transfer a liability, in an orderly transaction between market participants at the measurement date. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tiered value hierarchy that distinguishes between the following:

Level 1—Quoted market prices in active markets for identical assets or liabilities.

Level 2—Inputs other than Level 1 inputs that are either directly or indirectly observable, such as quoted market prices, interest rates and yield curves.

Level 3—Unobservable inputs for the asset or liability (i.e., supported by little or no market activity). Level 3 inputs include management's own assumptions about the assumptions that market participants would use in pricing the asset or liability (including assumptions about risk).

To the extent the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair values requires more judgement. Accordingly, the degree of judgement exercised by the Company in determining fair value is greatest for instruments categorized as Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible, as well as considers counterparty credit risk in its assessment of fair value.

Segment Information—Operating segments are defined as components of an enterprise for which discrete financial information is regularly reviewed by the chief operating decision maker in deciding how to allocate

resources and in assessing operating performance. The Company manages its operations as a single segment for the purposes of allocating resources, assessing performance, and making operating decisions. All tangible assets of the Company are held in the U.S.

Basic and Diluted Net Loss Per Share —The Company calculates basic net loss per share by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration of potential dilutive securities. Basic shares outstanding includes the weighted-average effect of the Company's pre-funded warrants to purchase shares of our common stock requiring little consideration upon exercise. Unvested restricted common shares as of December 31, 2023 and 2022 are not considered participating securities and as such are excluded from the weighted-average number of shares used for calculating basic and diluted net loss per share. Diluted net loss per share is computed by dividing the net loss by the sum of the weighted-average number of common shares outstanding during the period plus the dilutive effects of potentially dilutive securities outstanding during the period. Potentially dilutive securities include restricted common shares and stock options. The Company has generated a net loss for all periods presented, therefore diluted net loss per share is the same as basic net loss per share since the inclusion of potentially dilutive securities would be anti-dilutive.

Recently Adopted Accounting Pronouncements—In June 2016, the FASB issued ASC 2016-13 , *Financial Instruments - Credit Losses* ("ASC 2016-13"), a new standard intended to improve reporting requirements specific to loans, receivables and other financial instruments. The new standard requires that credit losses on financial assets measured at amortized cost be determined using an expected loss model, instead of the current incurred loss model, and requires that credit losses related to available-for-sale debt securities be recorded through an allowance for credit losses and limited to the amount by which carrying value exceeds fair value. We adopted the new standard on January 1, 2022 and have completed our assessment of the standard based on the composition of our portfolio of financial instruments. Our significant financial assets that are within the scope of the new standard consist of available for sale debt securities. There was no impact to our consolidated statements of operations and comprehensive loss or consolidated balance sheets upon adoption. See Note 4 for discussion of unrealized losses on our available for sale marketable securities.

Recently Issued Accounting Pronouncements—In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* ("ASU 2023-07"). This ASU requires disclosures of significant segment expenses and other segment items as well as incremental qualitative disclosures. The amendments in ASU 2023-07 apply to public entities, including those with a single reportable segment. This ASU is effective for all public companies for fiscal years beginning after December 15, 2024, and for interim periods beginning December 15, 2024. The Company may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted. The company has chosen not to early adopt this standard and is currently evaluating the potential impact of adopting this standard on its consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09") which establishes new income tax disclosure requirements in addition to modifying and eliminating certain existing requirements. Public business entities must apply the ASU's guidance to annual periods beginning after December 15, 2024. The company has chosen not to early adopt this standard and is currently evaluating the potential impact of adopting this standard on its consolidated financial statements.

3. LICENSE AND COLLABORATION AGREEMENTS

Asset Acquisition

In May 2022, we obtained worldwide exclusive rights to RLYB331, with Kymab Limited ("Sanofi") a preclinical antibody. We believe RLYB331 has the potential to address a significant unmet need for patients with severe anemias with ineffective erythropoiesis and iron overload, including beta thalassemia and a subset of lower risk myelodysplastic syndromes. Under the terms of the license agreement, we made an upfront payment to Sanofi of $ 3.0 million in the second quarter of 2022 for the exclusive license to KY1066. We could also be required to pay up to an aggregate of $ 43.0 million in development and regulatory milestones and up to an aggregate of $ 150.0 million in commercial milestones for a product in its first indication, plus tiered low-to-mid double digit percentages of such milestone amounts for up to three additional indications, and mid to high single digit royalties on net sales.

The license was accounted for as an asset acquisition as substantially all of the fair value of the asset acquired was concentrated in a single asset and thus the acquisition was deemed not to be a business combination. The

acquired license rights represent an IPR&D asset that was determined to have no alternative future use. Accordingly, the Company recorded an IPR&D charge of $ 3.1 million to research and development expense, including transaction costs associated with this asset acquisition of $ 0.1 million, in the accompanying consolidated statements of operations and comprehensive loss for the year ended December 31, 2022. The Company did no t record an IPR&D charge for the year ended December 31, 2023.

AbCellera Collaboration

In December 2022, the Company entered into a multi-year, multi-target collaboration with AbCellera to discover, develop, and commercialize novel antibody-based therapeutics for rare diseases. Under the terms of the agreement, AbCellera and Rallybio will co-develop and share the development costs of up to five rare disease therapeutic targets, which will be chosen together by both companies. At the point one party in the collaboration opts-out of future co-development cost sharing, that party will be entitled to a share of future profit sharing from commercialization of the collaboration target, dependent on the proportion of their co-development contributions compared to the total development costs of a target as defined within the agreement. The agreement also has defined profit sharing floors that correspond to the stage of development at the time a collaboration party opts-out of co-developing a target.

The Company concluded that the agreement with AbCellera will be accounted under the scope of ASC 808 as both parties will actively participate in joint operating activities and are exposed to significant risks and rewards that depend on the commercial success of those activities. Under ASC 808, certain transactions between collaborative arrangement participants should follow the accounting for revenue under ASC 606 when the collaborative arrangement participant is a customer.

The Company determined that co-development arrangement as defined in our agreement with AbCellera does not meet the definition of a customer as defined by ASC 606. As a result, these activities will be accounted for as research and development costs. Payments due because of the co-development will be recorded as research and development expense in the period such expenses are incurred and for payments owed to us from our collaboration partner for the reimbursement of research and development costs will be recorded as a contra-research and development expense in the period such expenses are incurred. Costs related to the AbCellera collaboration were $ 0.9 million for the year ended December 31, 2023. Costs related to the AbCellera collaboration were not material for the year ended December 31, 2022.

4. MARKETABLE SECURITIES

The amortized cost, gross unrealized holding gains, gross unrealized holding losses and fair value of our marketable securities by type of security as of December 31, 2023 and 2022 was as follows:

		DECEMBER 31, 2023			
(in thousands)	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Money market funds	Level 1	$ 14,538	$ —	$ —	$ 14,538
U.S. treasury securities	Level 1	35,976	48	(6)	36,018
U.S. government agency securities	Level 2	51,434	31	(58)	51,407
		$ 101,948	$ 79	$ (64)	$ 101,963

		DECEMBER 31, 2022			
(in thousands)	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Money market funds	Level 1	$ 12,647	$ —	$ —	$ 12,647
U.S. treasury securities	Level 1	39,372	—	(169)	39,203
U.S. government agency securities	Level 2	76,860	37	(82)	76,815
		$ 128,879	$ 37	$ (251)	$ 128,665

The fair values of marketable securities by classification in the consolidated balance sheets as of December 31, 2023 and 2022 was as follows:

(in thousands)	DECEMBER 31, 2023	DECEMBER 31, 2022
Cash and cash equivalents	$ 16,528	$ 16,629
Marketable securities	85,435	112,036
	$ 101,963	$ 128,665

The fair values of available-for-sale debt securities as of December 31, 2023 and 2022, by contractual maturity, are summarized as follows:

(in thousands)	DECEMBER 31, 2023	DECEMBER 31, 2022
Due in one year or less	$ 98,110	$ 127,667
Due after one year through two years	3,853	998
	$ 101,963	$ 128,665

The aggregate fair value of available-for-sale debt securities in an unrealized loss position as of December 31, 2023 and 2022 was $ 40.0 million and $ 70.0 million, respectively. As of December 31, 2023 and 2022, we did no t have any investments in a continuous unrealized loss position for more than twelve months. As of December 31, 2023, we believe that the cost basis of our available-for-sale debt securities is recoverable. No allowance for credit losses was recorded as of December 31, 2023 and 2022.

5. LEASES

We have operating leases for approximately nine thousand square feet of corporate office space. The weighted-average remaining lease term as of December 31, 2023 was 1.8 years. The weighted-average discount rate utilized on our operating lease liabilities as of December 31, 2023 was 4.00 %.

Operating leases are included in operating lease ROU assets, operating lease liabilities, and operating lease liabilities, noncurrent in our consolidated balance sheets as of December 31, 2023 and 2022.

The following table summarizes the presentation of the Company's operating lease as presented on the consolidated balance sheets:

(in thousands)	DECEMBER 31, 2023	DECEMBER 31, 2022
Assets:		
Operating lease right-of-use assets	$ 346	$ 524
Liabilities:		
Operating lease liabilities	$ 219	$ 181
Operating lease liabilities, noncurrent	173	374
Total operating lease liabilities	$ 392	$ 555

Future minimum lease payments from December 31, 2023 until the expiration of the operating lease are as follows:

(in thousands)	
2024	$ 230
2025	176
2026	—
Thereafter	—
Total lease payments	406
Less: imputed discount rate	(14)
Carrying value of operating lease liabilities	$ 392

The Company incurred $ 0.2 million in operating lease rent expense for both the years ended December 31, 2023 and 2022, respectively. Lease payments made were $ 0.2 million for both the years ended December 31, 2023 and 2022, respectively, with such amounts reflected in the consolidated statements of cash flows in operating activities.

6. BALANCE SHEET COMPONENTS

Property and Equipment—

Property and equipment consisted of the following as of December 31, 2023 and 2022:

(in thousands)	DECEMBER 31, 2023	DECEMBER 31, 2022
Computer and other equipment	$ 191	$ 180
Capitalized software	89	89
Furniture and fixtures	151	151
Leasehold improvements	338	338
Less accumulated depreciation	(523)	(373)
Property and equipment—net	$ 246	$ 385

Depreciation expense totaled $ 0.1 million and $ 0.2 million for the years ended December 31, 2023 and 2022, respectively.

Prepaid Expenses and Other Assets—

Prepaid expenses and other assets consisted of the following as of December 31, 2023 and 2022:

(in thousands)	DECEMBER 31, 2023	DECEMBER 31, 2022
Research and development	$ 2,067	$ 7,904
Insurance	446	933
Other prepaids	293	615
Other assets	2,054	1,050
	$ 4,860	$ 10,502

Accrued Expenses—

Accrued expenses consisted of the following as of December 31, 2023 and 2022:

(in thousands)	DECEMBER 31, 2023	DECEMBER 31, 2022
Research and development	$ 4,123	$ 3,582
Compensation and related expenses	3,166	4,703
Professional fees	332	510
Other	447	654
	$ 8,068	$ 9,449

7. STOCKHOLDERS' EQUITY

Common Stock

In August 2021, the Company completed its IPO, pursuant to which it issued and sold 7,130,000 shares of the Company’s common stock, inclusive of 930,000 shares sold pursuant to the full exercise of the underwriters’ option to purchase additional shares, at a public offering price of $ 13.00 per share. The gross proceeds from the IPO, including the exercise of the underwriter's option to purchase additional shares were $ 92.7 million and the net proceeds were approximately $ 83.0 million, after deducting underwriting discounts and commissions and other offering costs.

In November 2022, the Company completed a follow-on offering of approximately $ 54.8 million consisting of 5,803,655 shares of common stock, inclusive of 803,654 shares of common stock sold pursuant to the partial exercise of the underwriters' option to purchase additional shares at the price of $ 6.00 per share and to certain investors in lieu of common stock, pre-funded warrants to purchase up to an aggregate of 3,333,388 shares of common stock at a price of $ 5.9999 , which represents the per share public offering price for the shares less the $ 0.0001 per share exercise price for each pre-funded warrant. The net proceeds from the November 2022 follow-on offering were approximately $ 50.8 million, after deducting underwriting discounts and commissions and other offering costs.

The Company had 200,000,000 shares of common stock authorized as of December 31, 2023 and 2022, respectively, of which 37,829,565 and 37,837,369 shares were issued and outstanding as of December 31, 2023 and 2022, respectively.

Preferred Stock

The Company had 50,000,000 shares of preferred stock authorized as of December 31, 2023 and 2022, respectively, of which no shares were outstanding as of December 31, 2023 and 2022, respectively.

Pre-Funded Warrants

In connection with the November 2022 follow-on offering, the Company entered into an agreement with certain investors for pre-funded warrants in lieu of common stock to purchase up to an aggregate of 3,333,388 shares of common stock at a price of $ 5.9999 , which represents the per share public offering price at the November 2022 follow-on offering for common stock less a $ 0.0001 per share exercise price for each pre-funded warrant.

The Company may not effect the exercise of any pre-funded warrant, and a holder will not be entitled to exercise any portion of any pre-funded warrant if, upon giving effect to such exercise, the aggregate number of shares of common stock beneficially owned by the holder (together with its affiliates) would exceed 9.99 % of the number of shares of common stock outstanding immediately after giving effect to the exercise, which

percentage may be increased or decreased at the holder's election upon 61 days' notice to the Company subject to the terms of such pre-funded warrants, provided that such percentage may in no event exceed 19.99 %.

The Company's pre-funded warrant is a freestanding instrument that does not meet the definition of a liability pursuant to ASC 480 and does not meet the definition of a derivative pursuant to ASC 815. The pre-funded warrant is indexed to the Company's common stock and meets all other conditions for equity classification under ASC 480 and ASC 815. Accordingly, the pre-funded warrant was classified as equity and accounted for as a component of additional paid-in capital at the time of issuance. All of the pre-funded warrants related to our November 2022 follow-on offering remain outstanding and unexercised as of December 31, 2023.

Share-based Compensation

Share-based compensation which comprised of stock options, restricted stock awards, restricted stock units and the employee stock purchase plan is classified in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2023 and 2022 and was as follows:

	FOR THE YEAR ENDED DECEMBER 31,	
(in thousands)	**2023**	**2022**
Research and development	$ 4,606	$ 3,542
General and administrative	6,314	5,957
	$ 10,920	$ 9,499

2021 Equity Incentive Plan

In 2021, the board of directors adopted the Rallybio Corporation 2021 Equity Incentive Plan (the "2021 Plan"). The 2021 Plan reserves 5,440,344 for shares of the Company's common stock that have been issued in respect of outstanding equity awards granted prior to the registrant's IPO and for future issuances of shares to employees, directors and consultants in the form of stock options, SARs, restricted and unrestricted stock and stock units, performance awards and other awards that are convertible into or otherwise based on the Company's common stock. Dividend equivalents may also be provided in connection with awards under the 2021 Plan. The share pool will automatically increase on January 1st of each year from 2022 to 2031 by the lesser of (i) five percent of the number of shares of the Company's common stock outstanding as of such date and (ii) the number of shares of the Company's common stock determined by the board of directors on or prior to such date. On January 1, 2023 and January 1, 2022, the 2021 Plan share pool was automatically increased by 1,891,868 and 1,606,549 shares, respectively. As of December 31, 2023, the total number of shares of the Company's common stock that were issuable under the 2021 Plan was 6,775,026 shares, of which 2,284,232 shares remained available for future issuance.

The following table summarizes stock option activity for the year ended December 31, 2023:

Stock Options	**Number of Option Shares**	**Weighted-Average Exercise Price**	**Weighted-Average Contractual Term (in years)**	**Aggregate Intrinsic Value (in thousands)**
Outstanding at December 31, 2022	2,609,314	$ 13.01	8.8	$ —
Granted	2,017,183	$ 6.51		
Forfeited	(230,484)	$ 12.16		
Expired	(125,469)	$ 13.15		
Exercised	—	$ —		
Outstanding at December 31, 2023	4,270,544	$ 9.98	8.45	$ —
Options exercisable at December 31, 2023	1,590,886	$ 11.59	8.06	$ —

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the estimated fair value of the Company's common stock. Options outstanding and exercisable with an exercise price above the closing price as of December 31, 2023 are considered to have no intrinsic value. Using the Black-Scholes option pricing model, the weighted-average grant date fair value of stock options granted during the years ended December 31, 2023 and 2022 was $ 4.93 per share and $ 9.99 per share, respectively. Options vested during the years ended December 31, 2023 and 2022 with an exercise price above

the closing price are considered to have no intrinsic value. As of December 31, 2023, there was unrecognized share-based compensation expense related to unvested stock options of $ 16.9 million, which the Company expects to recognize over a weighted-average period of approximately 2.4 years.

The fair value of the stock options granted during the years ended December 31, 2023 and 2022 was determined using the Black-Scholes option pricing model with the following assumptions:

	FOR THE YEAR ENDED DECEMBER 31,	
	2023	2022
Expected volatility	88.38 % - 92.27 %	89.31 % - 91.62 %
Expected term (years)	5.50 - 6.08	5.50 - 6.08
Risk free interest rate	3.58 % - 4.52 %	1.42 % - 2.94 %
Expected dividend yield	—	—
Exercise price	$ 5.38 - $ 7.83	$ 7.54 - $ 15.04

A summary of the status of the Company's nonvested restricted common stock awards at December 31, 2023 and changes during the year ended December 31, 2023 was as follows:

Restricted Stock Awards	Shares	Weighted-Average Grant Date Fair Value Per Share
Nonvested restricted stock awards at December 31, 2022	1,006,368	$ 3.48
Granted	—	$ —
Vested	(553,668)	$ 3.20
Forfeited	(98,306)	$ 2.78
Outstanding nonvested restricted stock awards at December 31, 2023	354,394	$ 4.10

As of December 31, 2023, there was unrecognized share-based compensation expense related to unvested restricted stock awards of $ 1.3 million, which the Company expects to recognize over a weighted-average period of approximately 1.2 years.

A summary of the status of the Company's nonvested restricted common stock units at December 31, 2023 and changes during the year ended December 31, 2023 was as follows:

Restricted Stock Units	Shares	Weighted-Average Grant Date Fair Value Per Share
Nonvested restricted stock units at December 31, 2022	128,600	$ 11.12
Granted	110,075	$ 5.61
Forfeited	(6,500)	$ 9.11
Vested	(11,925)	$ 8.88
Outstanding nonvested restricted stock units at December 31, 2023	220,250	$ 8.55

As of December 31, 2023, there was unrecognized share-based compensation expense related to unvested restricted stock units of $ 1.0 million, which the Company expects to recognize over a weighted-average period of approximately 1.9 years.

2021 Employee Stock Purchase Plan

In connection with the Company's IPO, the board of directors adopted the Rallybio Corporation 2021 Employee Stock Purchase Plan (the "2021 ESPP"), which reserves 291,324 shares of the Company's common stock for future issuances under this plan. The share pool will automatically increase on January 1st of each year from 2022 to 2031 by the lesser of (i) one percent of the number of shares of the Company's common stock outstanding as of such date (ii) 582,648 shares of the Company's common stock, and (iii) the number of shares of the Company's common stock determined by the board of directors on or prior to such date. On January 1, 2023 and January 1, 2022, the 2021 ESPP share pool was automatically increased by 378,373 and 321,309 shares, respectively. As of December 31, 2023, the total number of shares of the Company's common stock that

were available for future issuance under the 2021 ESPP was 872,878 shares. During the years ended December 31, 2023 and 2022, the Company issued 79,283 and 38,845 shares, respectively, of the Company's common stock under the 2021 ESPP.

The 2021 ESPP allows eligible participants to purchase shares of our common stock through authorized payroll deductions. The purchase price of the shares will be not less than 85 % of the lower of the fair market value of our common stock on the first day of an offering or on the date of purchase.

For the years ended December 31, 2023 and 2022, the total share-based compensation for the 2021 ESPP was $ 0.2 million and $ 0.1 million, respectively.

8. INCOME TAXES

During each of the years ended December 31, 2023 and 2022 , the Company did not record any income tax benefits.

The Company's effective income tax rates are different from the federal statutory tax rates in 2023 and 2022 predominantly due to the valuation allowance, tax credits, and state taxes described below:

	2023	2022
U.S. federal statutory tax rate	21.0 %	21.0 %
State income taxes, net of federal income tax benefit	7.8 %	4.4 %
Tax credits	9.9 %	6.0 %
Other	(1.1)%	(2.8)%
Valuation allowance	(37.6)%	(28.6)%
Effective tax rate	0.0 %	0.0 %

Deferred income taxes represent the tax effect of transactions that are reported in different periods for financial and tax reporting purposes. The combined temporary differences and carryforwards of each tax paying component of the Company that give rise to a significant portion of the deferred income tax benefits and liabilities are as follows at December 31, 2023 and 2022:

	2023	2022
Net operating loss carryforwards	$ 37,230	$ 26,576
Amortization - non-174 intangibles	2,167	2,306
Section 174 capitalization	17,530	9,895
Research and development credits	17,729	10,242
Stock-based compensation	2,706	616
Other	917	580
Total deferred tax assets	78,279	50,215
Less valuation allowance	(78,279)	(50,215)
Net deferred tax assets	$ —	$ —

At December 31, 2023, the Company has approximately $ 135.1 million of federal net operating loss carryforwards, which do not expire, and approximately $ 134.6 million of state net operating loss carryforwards, which begin expiring in 2038.

At December 31, 2023, the Company has approximately $ 17.2 million of federal research and development tax credit carryforwards, which begin expiring in 2039, and approximately $ 0.5 million of state research and development tax credit carryforwards, which begin expiring in 2040.

The Company has provided a valuation allowance against the Company's deferred tax assets, since, in the opinion of management, based upon the history of losses by the Company and insufficient future federal and state taxable income; it is more likely than not that the benefits will not be realized. All or a portion of the remaining valuation allowance may be reduced in future years based on an assessment of earnings sufficient to fully utilize these potential tax benefits.

Effective January 1, 2022, a provision of the Tax Cuts and Jobs Act ("TCJA") changed the treatment of research and experimental ("R&E") expenditures under Section 174 of the Internal Revenue Code ("Code"). Previous to the TCJA being effective, businesses have had the option of deducting Section 174 expenses in the year incurred or capitalizing and amortizing the costs over five years. The new TCJA provision, however, eliminates this option and will require Section 174 expenses associated with research conducted in the U.S to be capitalized and amortized over a five-year period. For expenses associated with research outside of the United States, Section 174 expenses will be capitalized and amortized over a 15-year period.

Utilization of the U.S. federal and state net operating loss carryforwards and research and development tax credit carryforwards may be subject to an annual limitation under Section 382 and Section 383 of the Code, and corresponding provisions of state law, due to ownership changes that may have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income and tax liabilities. In general, an ownership change, as defined by Section 382 of the Code, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 5% over a three-year period.

The Company recently completed a Section 382 study and concluded that we underwent an ownership change as defined by the Code during the year ended December 31, 2021. We do not currently believe that the annual limitation will result in the expiration of any net operating losses or research and development tax credit carryforwards before utilization. Future ownership changes may limit our ability to utilize remaining tax attributes. Any carryforwards that will expire prior to utilization as a result of such additional limitations will be removed from deferred tax assets, with a corresponding reduction of the valuation allowance. Due to the existence of the valuation allowance, limitations created by future ownership changes, if any, will not impact the Company’s effective tax rate.

ASC 740 addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under ASC 740, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely that not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The Company has no material uncertain tax positions that qualify for either recognition or disclosure in consolidated financial statements.

It is the Company’s policy to recognize interest and/or penalties related to income tax matters in income tax expense. As of December 31, 2023 and 2022, the Company has accrued no interest and penalties related to uncertain tax positions. The Company does not have any outstanding U.S. federal income tax or material state and local tax matters for periods through December 31, 2023. There are no federal or state and local income tax returns currently under examination. As of December 31, 2023, the statute remains open for returns filed for the tax years ended: December 31, 2018; December 31, 2019; December 31, 2020; June 30, 2021; December 31, 2021; and December 31, 2022.

9. INVESTMENT IN JOINT VENTURE

The Company, through one of its wholly-owned subsidiaries, has a 50 % interest of the joint venture entity, REV-I. For the years ended December 31, 2023 and 2022 the Company funded $ 2.3 million and $ 0.3 million, respectively, associated with the Company's commitment and its share of REV-I development. The Company did not provide any additional financial support outside of capital contributions to REV-I during the years ended December 31, 2023 and 2022. While the Company held a 50 % interest in the joint venture as of December 31, 2023, based on management’s analysis, the Company is not the primary beneficiary of REV-I and accordingly, the entity is not consolidated in the Company's consolidated financial statements.

For the years ended December 31, 2023 and 2022, the Company recorded its allocable share of REV-I’s losses, which totaled $ 2.0 million and $ 1.1 million, respectively, as a loss on investment in joint venture within the consolidated statements of operations and comprehensive loss. After recognition of its share of losses for the period, the carrying value and maximum exposure to risk of the REV-I investment as of December 31, 2023 and December 31, 2022 was $ 0.2 million and $ 30 thousand, respectively, which was recorded in investment in joint venture in the accompanying consolidated balance sheets.

10. COMMITMENTS AND CONTINGENCIES

Purchase Commitments—The Company enters contracts in the normal course of business with contract research organizations and other third-party vendors for clinical trials and testing and manufacturing services. These contracts generally do not contain minimum purchase commitments and are cancellable by us upon written notice. Payments that may be due upon cancellation consist of payments for services provided or

expenses incurred prior to cancellation. As of December 31, 2023 and 2022 there were no amounts accrued related to termination charges.

11. NET LOSS PER COMMON SHARE

Basic and diluted loss per common share were calculated as follows:

	FOR THE YEAR ENDED DECEMBER 31,	
(in thousands except share and per share amounts)	**2023**	**2022**
Net loss	$ (74,564)	$ (66,654)
Weighted-average number of common shares outstanding, basic and diluted	40,447,388	31,821,311
Net loss per common share, basic and diluted	$ (1.84)	$ (2.09)

Basic net loss per share of common stock is based on the weighted-average number of shares of common stock outstanding during the period. Pre-funded warrants to purchase 3,333,388 shares of common stock that were issued in connection with the November 2022 follow-on offering were included in the weighted-average number of common shares outstanding for the years ended December 31, 2023 and 2022, respectively. The weighted-average number of common shares outstanding diluted for the years ended December 31, 2023 and 2022 excludes approximately 4.8 million and 3.7 million stock options and unvested restricted stock awards and units, respectively, which were not dilutive.

12. SUBSEQUENT EVENTS

On February 6, 2024, the Company announced a prioritization of its portfolio and a workforce reduction to focus resources on its Phase 2-ready clinical stage programs, RLYB212 and RLYB116.

As part of this effort, the Company eliminated approximately 45 % of its positions. As a result of these actions, the Company expects to incur charges of approximately $ 3.3 million, excluding share-based compensation expense. The charges related to the workforce reduction are cash-based expenditures related primarily to one-time severance and benefit payments. The Company expects to recognize substantially all charges related to the workforce reduction in the quarter ending March 31, 2024. These estimates are subject to assumptions and actual results may differ.

Exhibit 21.1

SUBSIDIARIES

Subsidiary Name	Jurisdiction of Organization
Rallybio, LLC	Delaware
Rallybio IPA, LLC	Delaware
Rallybio IPB, LLC	Delaware
IPC Research, LLC	Delaware
Rallybio IPE, LLC	Delaware
Rallybio IPF, LLC	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-271748 on Form S-3 and Registration Statement Nos. 333-258383, 333-265443, and 333-271805 on Form S-8 of our report dated March 12, 2024, relating to the financial statements of Rallybio Corporation appearing in this Annual Report on Form 10-K for the year ended December 31, 2023.

/s/ Deloitte & Touche LLP

Hartford, Connecticut
March 12, 2024

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Stephen Uden, certify that:

1. I have reviewed this Annual Report on Form 10-K of Rallybio Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 12, 2024

By: /s/ Stephen Uden

Stephen Uden M.D.

Chief Executive Officer, President and Director

(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jonathan I. Lieber, certify that:

1. I have reviewed this Annual Report on Form 10-K of Rallybio Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 12, 2024

By: /s/ Jonathan I. Lieber

Jonathan I. Lieber
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Rallybio Corporation (the "Company") on Form 10-K for the period ending December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 12, 2024

By: /s/ Stephen Uden

Stephen Uden, M.D.
Chief Executive Officer, President and Director
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Rallybio Corporation (the "Company") on Form 10-K for the period ending December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 12, 2024

By: /s/ Jonathan I. Lieber

Jonathan I. Lieber
Chief Financial Officer
(Principal Financial Officer)

Exhibit 97

RALLYBIO CORPORATION
POLICY FOR RECOUPMENT OF INCENTIVE COMPENSATION

1. **Introduction**

In accordance with Section 10D of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the regulations thereunder, the Board of Directors (the "Board") of Rallybio Corporation (the "Company") has adopted a policy (the "Policy") providing for the Company's recoupment of certain incentive-based compensation received by Covered Executives (as defined below) in the event that the Company is required to prepare an accounting restatement due to its material noncompliance with any financial reporting requirement under the securities laws. This Policy is designed to comply with, and shall be construed and interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated under the Exchange Act and Listing Rule 5608 of the corporate governance rules of The Nasdaq Stock Market.

1. **Administration**

Administration and enforcement of this Policy is delegated to the Compensation Committee of the Board (as constituted from time to time, and including any successor committee, the "Committee"). The Committee shall make all determinations under this Policy in its sole discretion. Determinations of the Committee under this Policy need not be uniform with respect to any or all Covered Executives and will be final and binding.

1. **Effective Date**

This Policy shall be effective as of October 2, 2023 (the "Effective Date") and shall apply only to Covered Compensation (as defined below) that is received by Covered Executives on or after the Effective Date.

1. **Covered Executives**

This Policy covers each current or former officer of the Company subject to Section 16 of the Exchange Act (each, a "Covered Executive").

1. **Covered Compensation**

This Policy applies to any cash-based and equity-based incentive compensation, bonuses, and awards that are received by a Covered Executive and that were based, wholly or in part, upon the attainment of any financial reporting measure ("Covered Compensation"). For the avoidance of doubt, none of the following shall be deemed to be Covered Compensation: base salary, a bonus that is paid solely at the discretion of the Committee or Board and not paid from a bonus pool determined by satisfying a financial reporting measure performance goal, and cash or equity-based awards that are earned solely upon satisfaction of one or more subjective or strategic standards. This Policy shall apply to any Covered Compensation received by an employee who served as a Covered Executive at any time during the performance period for that Covered Compensation.

1. **Financial Restatements; Recoupment**

In the event that the Company is required to prepare an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (such an accounting restatement, a "Restatement"), the Committee shall review the Covered Compensation received by a Covered Executive during the three-year period preceding the Required Financial Restatement Date as well as any transition period that results from a change in the Company's fiscal year within or immediately following those three completed fiscal years. Regardless of whether the Company filed the restated financial statements, the Committee shall, to the full extent permitted by governing law, seek recoupment of any Covered Compensation, whether in the form of cash or equity, received by a Covered Executive (computed without regard to any taxes paid), if and to the extent:

a. the amount of the Covered Compensation was calculated based upon the achievement of certain financial results that were subsequently the subject of a Restatement; and

a. the amount of the Covered Compensation that would have been received by the Covered Executive had the financial results been properly reported would have been lower than the amount actually awarded (any such amount, "Erroneously-Awarded Compensation").

To the extent Covered Compensation was based on the achievement of a financial reporting measure, but the amount of such Covered Compensation was not awarded or paid on a formulaic basis, the Committee shall determine the amount, if any, of such Covered Compensation that is deemed to be Erroneously-Awarded Compensation.

For purposes of this Policy, the 'Required Financial Restatement Date" is the earlier to occur of:

a. the date the Board, a committee of the Board, or any officer or officers authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare a Restatement; or

a. the date a court, regulator, or other legally authorized body directs the Company to prepare a Restatement.

For the avoidance of doubt, a Covered Executive will be deemed to have received Covered Compensation in the Company's fiscal period during which the financial reporting measure specified in the award is attained, even if the Covered Executive remains subject to additional payment conditions with respect to such award.

1. **Method of Recoupment**

The Committee will determine, in its sole discretion, the method for recouping Erroneously-Awarded Compensation, which may include, without limitation:

i. requiring reimbursement of cash incentive compensation previously paid;

i. cancelling or rescinding some or all outstanding vested or unvested equity (and/or equity-based) awards;

i. adjusting or withholding from unpaid compensation or other set-off to the extent permitted by applicable law; and/or

i. reducing or eliminating future salary increases, cash-based or equity-based incentive compensation, bonuses, awards or severance.

1. **Impracticability Exceptions**

The Committee shall not seek recoupment of anyErroneously-Awarded Compensation to the extent it determines that:

a. the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount oErroneously-Awarded Compensation to be recovered;

a. recovery would violate home country law where that law was adopted prior to November 28, 2022; and/or

a. recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to Company employees, to fail to meet the requirements of Sections 401(a)(13) and 411(a) of the Internal Revenue Code of 1986, as amended, and the regulations thereunder.

1. **No Indemnification**

For the avoidance of doubt, the Company shall not indemnify any Covered Executive against the loss of any Erroneously-Awarded Compensation or any Covered Compensation that is recouped pursuant to the terms of this Policy, or any claims relating to the Company's enforcement of its rights under this Policy.

1. **Severability**

If any provision of this Policy or the application of any such provision to any Covered Executive shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

1. **Amendments**

The Committee may amend, modify or terminate this Policy in whole or in part at any time and may adopt such rules and procedures that it deems necessary or appropriate to implement this Policy or to comply with applicable laws and regulations.

1. **No Impairment of Other Remedies**

The remedies under this Policy are in addition to, and not in lieu of, any legal and equitable claims the Company may have, the Company's ability to enforce, without duplication, the recoupment provisions set forth in any separate Company policy or in any Company plan, program or agreement (each, a "Separate Recoupment Policy" and collectively, the "Separate Recoupment Policies"), or any actions that may be imposed by law enforcement agencies, regulators or other authorities. Notwithstanding the foregoing, in the event that there is a conflict between the application of this Policy to a Covered Executive in the event of a Restatement and any additional recoupment provisions

set forth in a Separate Recoupment Policy to which a Covered Executive is subject, the provisions of this Policy shall control. The Company may also adopt additional Separate Recoupment Policies in the future or amend existing requirements as required by law or regulation.

September 13, 2023