UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

OR

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

Commission File Number: 001-39385

RELAY THERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**47-3923475**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
60 Hampshire Street Cambridge, MA	**02139**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 370-8837

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 $0.001 per share	**RLAY**	**NASDAQ Global Market**

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

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

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

Indicate by check mark whether the Registrant: (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 ☒ NO ☐

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

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

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

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

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

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

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

The aggregate market value of common stock held by non-affiliates of the Registrant based on the closing price of the Registrant's common stock as reported on the Nasdaq Global Market on June 30, 2025, the last business day of the Registrant's most recently completed second quarter, was approximately $585.5 million. In determining the market value of non-affiliate common stock, shares of the Registrant's common stock beneficially owned by officers, directors and affiliates have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of Registrant's Common Stock outstanding as of February 20, 2026 was 178,725,809.

DOCUMENTS INCORPORATED BY REFERENCE

The Registrant intends to file a definitive proxy statement pursuant to Regulation 14A relating to the 2026 Annual Meeting of Stockholders within 120 days of the end of the registrant's fiscal year ended December 31, 2025. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein.

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SUMMARY OF THE MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

- We have never successfully completed any large-scale, pivotal clinical trials, and we may be unable to do so for any product candidates we develop. Clinical product development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

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

- Positive data from preclinical or early clinical studies of our product candidates are not necessarily predictive of the results of later clinical studies and any future clinical trials of our product candidates. If we cannot replicate the positive data from our preclinical or early clinical studies of our product candidates in our future clinical trials, we will be unable to successfully develop, obtain regulatory approval for, and commercialize our product candidates.

- Our current or future clinical trials or those of future collaborators or licensees may reveal significant adverse events not seen in our preclinical or nonclinical studies or early clinical data and may result in a safety profile that would inhibit regulatory approval or market acceptance of any of our product candidates.

- Although we intend to explore other therapeutic opportunities, in addition to the product candidates that we are currently developing, we may fail to identify viable new product candidates for clinical development for a number of reasons. If we fail to identify additional potential product candidates, our business could be materially harmed.

- The incidence and prevalence for target patient populations of our product candidates have not been established with precision. If the market opportunities for our product candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability will be adversely affected, possibly materially.

- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

- If we are not able to obtain, or if delays occur in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

- We have relied on, and expect to continue to rely on, third parties to conduct our current and future clinical trials of our product candidates, as well as investigator-sponsored clinical trials of our product candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

- We are a biopharmaceutical company with a limited operating history. We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future. We have no products approved for commercial sale and have not generated any revenue from product sales.

- We will need to raise substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate some of our product development programs or commercialization efforts.

- If we are unable to adequately protect our proprietary technology or obtain and maintain patent protection for our technology and products 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 commercialize our technology and products will be impaired.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains express or implied "forward-looking statements," within the meaning of the Private Securities Litigation Reform Act of 1995, that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements contained in this Annual Report on Form 10-K include, but are not limited to, implied or express statements about:

- the initiation, enrollment, timing, progress, results, and cost of our product candidates and research and development programs and our current and future preclinical and clinical studies, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, as well as the period during which the results of the trials will become available;
- the identification of research priorities, reallocation of resources among programs, and application of a risk-mitigated strategy to efficiently discover and develop product candidates, including by applying learnings from one program to other programs and from one modality to our other modalities, as well as the potential expected benefits therefrom;
- the potential safety and efficacy of our product candidates and the therapeutic implications of clinical and preclinical data;
- the manufacture of our drug substances, delivery vehicles, and product candidates for preclinical use, for clinical trials, and, on a larger scale, for commercial use, if approved;
- our relationships with our third-party strategic collaborators and licensees and their ability to continue research and development and commercialization activities relating to our development candidates and product candidates;
- the funding for our operations necessary to complete further development and commercialization of our product candidates;
- our plans to seek regulatory approval of our product candidates;
- the pricing and reimbursement of our product candidates, if approved;
- the implementation of our business model and strategic plans for our business, product candidates, and technology;
- the scope of protection for intellectual property rights covering our product candidates and technology;
- estimates of our future expenses, revenues, capital requirements, and our needs for additional financing;
- the potential benefits of strategic collaboration and/or license agreements with collaborators and/or licensees with development, regulatory, and commercialization expertise;
- future agreements with third parties in connection with the commercialization of product candidates and any other approved product;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- our financial performance;
- the rate and degree of market acceptance of our product candidates;
- regulatory developments in the United States and foreign countries;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our ability to produce our products or product candidates with advantages in turnaround times or manufacturing cost;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific, clinical, or management personnel;
- the impact of laws and regulations on our business and programs;

- developments relating to our competitors and our industry;

- the effect of public health epidemics or outbreaks of an infectious disease and ongoing geopolitical conflicts, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations, including, but not limited to, our preclinical studies and current and future clinical trials;

- general economic and market conditions, including, among others, inflation, interest rates, tax rates, economic uncertainty, the actual or perceived failure or financial difficulties of additional financial institutions, and economic and trade sanctions, including their effect on our results of operations; and

- other risks and uncertainties, including those listed under the caption "Risk Factors."

In some cases, you can identify forward-looking statements by terminology such as "may," "can," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "forecasts," "goal," "likely," "predicts," "potential," "projects," "will," "might," "could," "continue," or the negative of these terms or other comparable terminology. These statements are only predictions. All statements other than statements of historical facts are statements that could be deemed forward-looking statements. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed above under "Summary of the Material Risks Associated with Our Business," those listed below under the section titled "Risk Factors" and elsewhere in this Annual Report on Form 10-K. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this Annual Report on Form 10-K and the documents that we reference in this Annual Report on Form 10-K and have filed with the Securities and Exchange Commission, or the SEC, as exhibits hereto completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this Annual Report on Form 10-K represent our views as of the date of this Annual Report on Form 10-K. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

This Annual Report on Form 10-K also contains estimates, projections, and other information concerning our industry, our business, and the markets for our product candidates. Information that is based on estimates, forecasts, projections, market research, or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from our own internal estimates and research, as well as from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources. While we are not aware of any misstatements regarding any third-party information presented in this Annual Report on Form 10-K, their estimates, in particular as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed under the section titled "Risk Factors" and elsewhere in this Annual Report on Form 10-K.

PART I

Except where the context otherwise requires or where otherwise indicated, the terms "Relay Therapeutics," "we," "us," "our," "our company," the "Company," and "our business" refer to Relay Therapeutics, Inc. and its consolidated subsidiaries.

Item 1. Business.

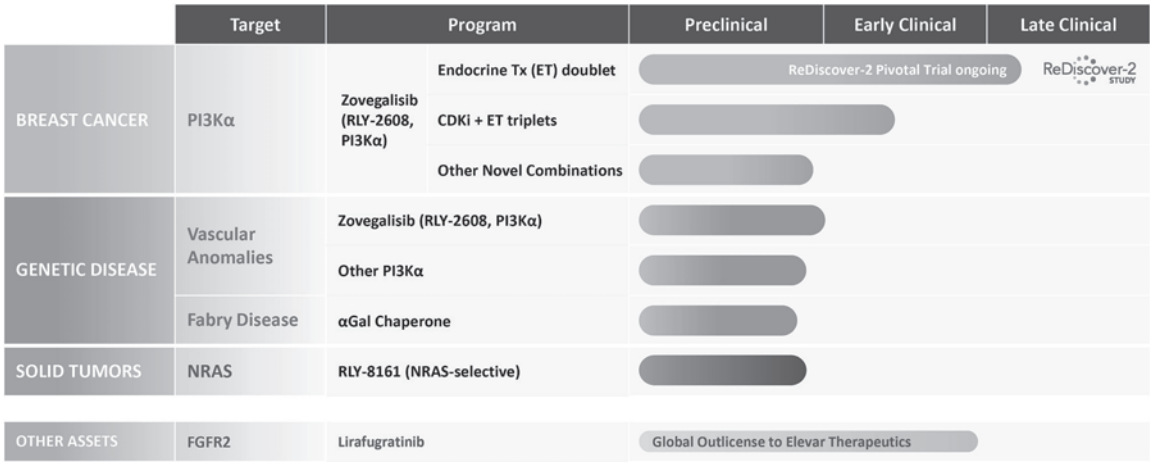
Overview

We are a clinical-stage, small molecule precision medicine company developing potentially life-changing therapies for patients living with cancer and genetic disease. Our Dynamo® platform integrates an array of leading-edge computational and experimental approaches designed to drug protein targets that have previously been intractable or inadequately addressed.

Precision medicine emerged as an approach for disease treatment as the understanding of the link between genetic alterations, protein dysfunction and diseases evolved. Precision medicine aims to specifically and potently drug genetically validated target proteins (i.e., genetic variants potentially implicated in biology of disease). However, some target proteins thus far have been intractable or inadequately addressed using conventional drug discovery tools. While conventional approaches are well-suited to solving some drug discovery problems such as orthosteric site kinase inhibitors, their reliance on static images of protein fragments limits their ability to gain accurate insights into the dynamic behavior of proteins in their natural state, which in turn limits their ability to discover medicines with exquisite specificity. Our approach pivots the understanding of protein targets from the industry-standard, static view, to a novel paradigm based on fundamental insights into protein motion. We then apply these novel insights into protein motion to drug discovery and design, which we term Motion-Based Drug Design®.

We have deployed our technology platform to build a pipeline of product candidates to address targets in precision medicine where there is clear evidence linking target proteins to disease and where molecular diagnostics can unambiguously identify relevant patients for treatment. We believe this approach will increase the likelihood of successfully translating a specific pharmacological mechanism into clinical benefit.

We are advancing a pipeline of medicine candidates to address targets in precision oncology and genetic disease, including zovegalisib (RLY-2608), our lead product candidate discussed below.



Zovegalisib (RLY-2608). Zovegalisib is the first known allosteric, pan-mutant and isoform-selective phosphoinostide 3 kinase alpha, or PI3Kα, inhibitor in clinical development. It is the lead program in our efforts to discover and develop mutant selective inhibitors of PI3Kα.

- ***Breast Cancer and Solid Tumors***

  - ReDiscover Trial. In December 2021, we dosed the first patient in a first-in-human clinical trial for zovegalisib, or the ReDiscover Trial. Since then, we have predominantly focused on evaluating zovegalisib in combination with fulvestrant for patients with HR+, HER2–, PI3Kα-mutated, locally advanced or metastatic breast cancer. We are also advancing triplet combination arms with zovegalisib, fulvestrant and cyclin dependent kinase 4/6, or CDK 4/6, inhibitors, or atirmociclib, the investigative selective-CDK4 inhibitor from Pfizer Inc., or Pfizer. In the second quarter of 2025, we initiated a global Phase 3 registrational study, or the ReDiscover-2 Trial, which is designed to evaluate the safety and efficacy of zovegalisib plus fulvestrant in PI3Kα-mutated, HR+/HER2- advanced breast cancer patients previously treated with a CDK4/6 inhibitor. The comparator arm in the ReDiscover-2 Trial is capivasertib plus fulvestrant. In February 2026, we announced that the U.S. Food and Drug Administration, or FDA, granted Breakthrough Therapy designation to zovegalisib in combination with fulvestrant for the treatment of adults with

PIK3CA mutant HR+/HER2- locally advanced or metastatic breast cancer following recurrence or progression on or after treatment with a CDK4/6 inhibitor.

- Clinical Data. In June 2025, we announced updated interim clinical data for the zovegalisib plus fulvestrant arm of the ReDiscover Trial with a data cut-off date of March 26, 2025, and in December 2025, we announced an efficacy subset analysis of interim clinical data for zovegalisib at the San Antonio Breast Cancer Symposium 2025 with a data cut-off date of October 15, 2025. These interim clinical data are discussed further below in "Our Product Pipeline and Programs —Our Lead Product Candidate – Breast Cancer and Solid Tumors - Interim Clinical Data." We believe that while the clinical data from the ReDiscover Trial disclosed to date are preliminary, the data suggest differentiated interim efficacy signals in the specified patient population and support selective target engagement across doses and mutation types with an encouraging interim safety and tolerability profile.

- ***Vascular Anomalies***

  - ReInspire Trial. In the first quarter of 2025, we initiated the global Phase 1/2 clinical trial for zovegalisib in patients with PIK3CA-related overgrowth spectrum, or PROS, and vascular anomalies driven by PIK3CA mutations, or the ReInspire Trial. Enrollment is continuing in this clinical trial.

In addition to the programs mentioned above, we are progressing our NRAS-selective inhibitor, RLY-8161, to address NRAS-mutated solid tumors as well as our non-inhibitory chaperone for Fabry disease. We are also advancing early-stage discovery programs across both precision oncology and genetic diseases.

Our Strategy

Our mission is to leverage unique insights into protein motion to transform the lives of patients suffering from debilitating and life-threatening diseases through the discovery, development and commercialization of small molecule therapies. We believe that, by placing protein motion at the heart of Motion-Based Drug Design discovery, our unique Dynamo® platform has the potential to address previously intractable or inadequately addressed precision medicine targets. To accomplish this, we have built a team that shares our commitment to patients and we intend to rapidly advance our precision medicine pipeline of product candidates with a focus on the highest value opportunities. The key elements of our strategy are to:

Rapidly advance our PI3Kα franchise and other programs through clinical development with the goal of reaching as many patients as possible. We believe that zovegalisib has the potential to address a significant portion of patients globally with HR+, HER2- breast cancer with a PI3Kα mutation, one of the largest patient populations for a precision oncology medicine. We initiated the Phase 3 ReDiscover-2 Trial in the second quarter of 2025 and continue to prioritize development of the zovegalisib doublet and triplet combinations with the aim of reaching breast cancer patients across both CDK4/6-experienced and -naïve settings. Additionally, in the first quarter of 2025, we advanced zovegalisib in vascular anomalies through the initiation of our ReInspire Trial, expanding our PI3Kα franchise to genetic disease. We plan to continue to conduct our clinical studies in genetically-defined patient populations. If we are successful in generating clinically meaningful and differentiated data for our programs, we plan to meet with regulatory authorities to discuss potential approval pathways.

Harness the insights and data generated from our drug discovery platform against intractable or inadequately addressed precision medicine targets, with current focus on oncology and genetic diseases. We are committed to deploying our Dynamo® platform against genetically validated targets, taking on some of the toughest technical drug discovery challenges and creating novel medicines against those targets that can rapidly attain clinical proof-of-concept and address significant unmet medical needs. Our focus is on precision oncology where there are clear genetic driver alterations in the tumor genome, and genetic disease where the causal mutations are present at birth.

Selectively enter into strategic partnerships to maximize the value of our platform and pipeline. We intend to build a fully integrated biopharmaceutical company and independently pursue the development and commercialization of our key product candidates. Given our potential to generate novel product candidates addressing a wide variety of therapeutic indications, we may enter into strategic partnerships around certain targets, product candidates, disease areas or geographies if we believe these collaborations or licenses could accelerate the development and commercialization of our product candidates and allow us to realize additional potential in our product candidates and our platform. For example, in June 2024, we entered into a global clinical trial collaboration with Pfizer for the development of zovegalisib in combination with fulvestrant and atirmociclib, Pfizer's investigative selective-CDK4 inhibitor, in patients with PI3Kα-mutated, HR+, HER2- metastatic breast cancer. Additionally, in December 2024, we entered into an exclusive global licensing agreement, or the Elevar Agreement, with Elevar Therapeutics, Inc., or Elevar, pursuant to which Elevar was granted global development and commercialization rights for lirafugratinib (RLY-4008), our selective oral small molecule inhibitor of fibroblast growth factor receptor 2, or FGFR2. Outside of the Elevar Agreement, we currently retain full development and commercialization rights to our pipeline of active precision medicine programs.

Our Dynamo® Platform

Dynamo was built to capitalize on experimental and computational techniques to develop medicines against protein targets with greater specificity and potency. Using our Dynamo platform, we pivot from industry standard approaches, which are based on static structures and often rely on incomplete protein fragments, to a novel drug-discovery paradigm based on fundamental insights into protein motion, which we term Motion-Based Drug Design®. We leverage insights from our platform to develop novel, motion-based hypotheses for how to drug target proteins. We can then more rapidly identify and optimize effective lead compounds by integrating powerful experimental and computational tools to sample a much broader range of chemical space than is possible using conventional approaches, which are labor intensive and require significant experimental effort.

Our platform integrates a broad and tailored array of leading edge experimental and computational approaches to gain fundamental insights into protein function. We deploy the power of our Dynamo platform in three key phases of Motion-Based Drug Design discovery. We first understand how to drug the protein by developing a detailed mechanistic understanding of the dynamic behavior of the target protein and by identifying pockets where binding of a small molecule can impact protein function, which allows us to generate a target modulation hypothesis. Our platform then aids in efficient hit identification, or the identification of chemical starting points through an integrated system of experimental and virtual screens. This enables rapid lead optimization until a development candidate is selected by computationally prioritizing compounds for experimental evaluation. As each cycle generates new learnings for both our team and our underlying machine learning models, our successful iteration of this process continuously improves our understanding of protein motion which leads to a more effective and efficient drug discovery process.

Our Product Pipeline and Programs

While our Dynamo platform could potentially be applied to a wide range of disease-associated protein targets, we focus on precision medicine targets, currently specifically in oncology and genetic diseases, for which alterations in specific genes are known to cause disease. The genetic diseases we pursue include cancers with clear genetic driver alterations in the tumor genome, as well as monogenic diseases where the causal mutations are present at birth.

See "—Overview" above for a table that summarizes our current portfolio of product candidates and programs.

Our Lead Product Candidate

Our lead product candidate in clinical development, zovegalisib, is the first known investigational allosteric, pan-mutant and isoform-selective inhibitor of PI3Kα, which is discussed further below.

Overview

Zovegalisib is the lead program in our efforts to discover and develop mutant selective inhibitors of PI3Kα. PI3Kα is the most frequently mutated kinase in all cancers and all vascular anomalies. Traditionally, the development of PI3Kα inhibitors has focused on the active, or orthosteric, site. The therapeutic index of orthosteric inhibitors is limited by the lack of clinically meaningful selectivity for mutant versus wild-type PI3Kα and off-isoform activity. Toxicity related to inhibition of wild-type PI3Kα and other PI3K isoforms results in sub-optimal inhibition of mutant PI3Kα with reductions in dose intensity and frequent discontinuation. The Dynamo® platform enabled the discovery of zovegalisib, what we believe to be the first known allosteric, pan-mutant, and isoform-selective PI3Kα inhibitor designed to overcome these limitations. By solving the full-length cryo-electron microscopy, or Cryo-EM, structure of PI3Kα and performing computational long time-scale molecular dynamic simulations to elucidate conformational differences between wild-type and mutant PI3Kα, we were able to leverage these insights to support the design of zovegalisib.

We dosed the first patient in the ReDiscover Trial in December 2021. Since then, we have predominantly focused on evaluating zovegalisib in combination with fulvestrant for patients with HR+, HER2–, PI3Kα-mutated, locally advanced or metastatic breast cancer. We are also advancing triplet combination arms with zovegalisib, fulvestrant and CDK 4/6 inhibitors or atirmociclib, the investigative selective-CDK4 inhibitor from Pfizer. In the second quarter of 2025, we initiated the ReDiscover-2 Trial, which is designed to evaluate the safety and efficacy of zovegalisib plus fulvestrant in PI3Kα-mutated, HR+/HER2- advanced breast cancer patients previously treated with a CDK4/6 inhibitor. The comparator arm in the ReDiscover-2 Trial is capivasertib plus fulvestrant. In February 2026, we announced that the FDA granted Breakthrough Therapy designation to zovegalisib in combination with fulvestrant for the treatment of adults with PIK3CA mutant HR+/HER2- locally advanced or metastatic breast cancer following recurrence or progression on or after treatment with a CDK4/6 inhibitor.

We believe that while the interim clinical data from the ReDiscover Trial disclosed to date are preliminary, the data suggest differentiated interim efficacy signals in the specified patient population and support selective target engagement across doses and mutation types with an encouraging interim safety and tolerability profile. Zovegalisib interim clinical data are discussed in further detail below in "—Interim Clinical Data."

In addition to breast cancer, we have also advanced zovegalisib in genetic disease. In the first quarter of 2025, we initiated the ReInspire Trial for zovegalisib in patients with PROS and anomalies driven by PIK3CA mutations. Enrollment is continuing in this clinical trial.

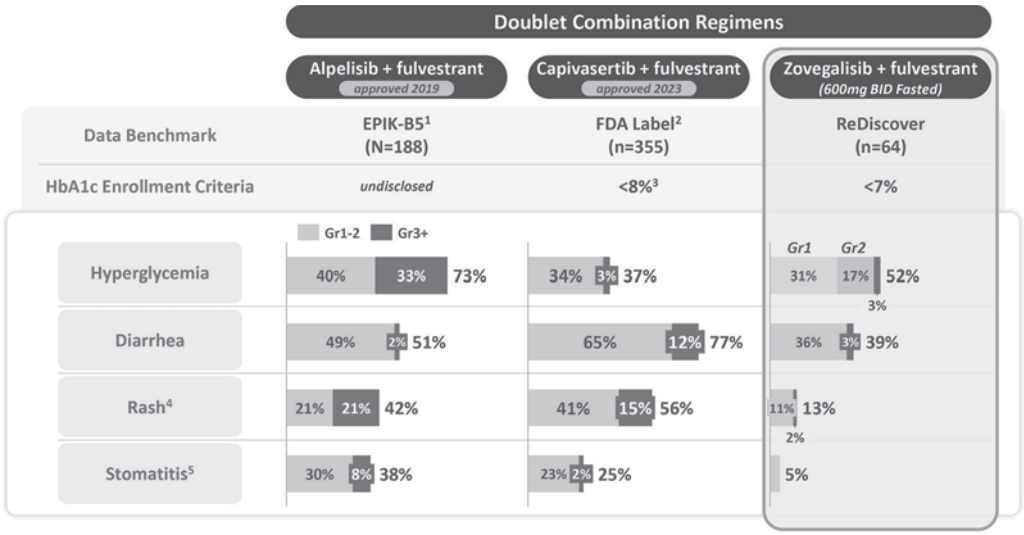
We believe zovegalisib has the potential, if approved, to address a significant portion of the approximately 140,000 patients with HR+, HER2- breast cancer with a PI3Kα mutation per year in the United States and the estimated 170,000 patients with vascular anomalies driven by a PI3Kα mutation per year in the United States.

Limitations of current PI3Kα inhibitors

Traditionally, the development of PI3Kα inhibitors has focused on the active, or orthosteric site. This site and its location make selectivity for PI3Kα over other PI3K isoforms and for mutant PI3Kα over wild-type PI3Kα difficult, and they do not enable pan-mutant coverage. Though these existing inhibitors have shown clinical activity in breast cancer as both monotherapy and in combination with hormonal therapy and cell cycle therapy, as well as anecdotal monotherapy responses in patients with PI3Kα mutations in other tumor types, the therapeutic index of such orthosteric inhibitors is limited by the lack of clinically meaningful selectivity for mutant versus wild-type PI3Kα and off-isoform activity. Toxicity related to inhibition of wild-type PI3Kα, other PI3K isoforms, or other nodes in the PI3K pathway results in sub-optimal inhibition of mutant PI3Kα with reductions in dose intensity and frequent discontinuation. These agents are generally limited by high rates of severe hyperglycemia, which is an on-target toxicity, and by gastrointestinal toxicity, which may be related to inhibition of other PI3K family members, including PI3Kδ.

Zovegalisib, the first known investigational allosteric, pan-mutant, and isoform-selective PI3Kα inhibitor, was designed to overcome these limitations. (**Figure 1**)

Figure 1: Non-selective inhibition of the PI3Kα pathway leads to toxicity challenges.



1. EPIK-B5, SABCS 2025 #RF7-02; 2. FDA Prescribing Information; 3. per CAPItello-291 enrollment criteria; 4. Rash for alpelisib references the cumulative sum of rates of rash and rash maculo-papular from the EPIK-B5 study, and may include overlap. Rash for capivasertib references Cutaneous Adverse Reactions grouped term includes a number of preferred terms listed in FDA Prescribing Information; 5. Stomatitis for alpelisib references the cumulative sum of rates of stomatitis and mucosal inflammation from the EPIK-B5 study, and may include overlap; ReDiscover preliminary data as of 03/26/2025.
Note: These data are derived from different clinical trials at different points in time, with differences in molecule composition, trial design and patient populations. As a result, cross-trial comparisons cannot be made, and no head-to-head clinical trials have been conducted.

Our solution, zovegalisib

Given the existence of mutations in PI3Kα with different biological mechanisms underlying aberrant activity, we believe the broadest opportunity is through the development of "pan-mutant" inhibitors of PI3Kα. Addressing the challenge of mutant selectivity required us to express and then solve the structure of the full-length PI3Kα protein. This structure, which to our knowledge had previously not been solved, represented a technical challenge because PI3Kα is a membrane-bound protein. This type of protein is typically difficult both to purify in large quantities and to crystallize. Nonetheless, we were able to obtain the structure of full-length PI3Kα using Cryo-EM. The three-dimensional structure of PI3Kα was determined by collecting data from two-dimensional electron microscopic projections of thin layers of protein. The resulting three-dimensional protein structure provided us with fundamental insights into the mechanism of activation of PI3Kα and the impact of mutations on its function. The integration of these structural insights with a combination of experimental and computational techniques has led to zovegalisib, the first molecule derived from these efforts and the first known allosteric, pan-mutant and isoform-selective PI3Kα inhibitor in clinical development.

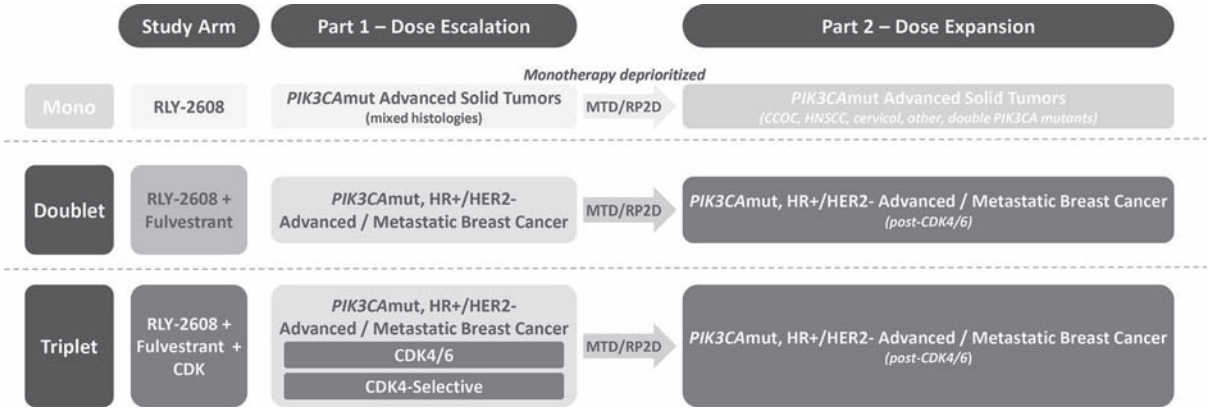
Breast Cancer and Solid Tumors

PI3Kα is the most frequently mutated kinase in all cancers, with oncogenic mutations detected in about 14% of patients with solid tumors. We believe zovegalisib has the potential to address a significant portion of the approximately 140,000 patients with HR+, HER2- breast cancer with a PI3Kα mutation per year in the United States, one of the largest patient populations for a precision oncology medicine.

Clinical Development

The ReDiscover Trial is designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary antitumor activity of zovegalisib, and consists of three separate arms (**Figure 2**). Initial development began with the monotherapy arm assessing zovegalisib as a single agent for patients with unresectable or metastatic solid tumors with PI3Kα mutation. Current development efforts prioritize combination arms for patients with PI3Kα-mutant, HR+, HER2- locally advanced or metastatic breast cancer, including the doublet arm evaluating zovegalisib in combination with fulvestrant and the triplet arm evaluating triplet combinations with CDK4/6 inhibitors and selective CDK4 inhibitor, atirmociclib. Each arm has two parts, a dose escalation (part 1) to determine the maximum tolerated dose and/or recommended Phase 2 dose, followed by a dose expansion (part 2) to evaluate zovegalisib in genomically defined populations.

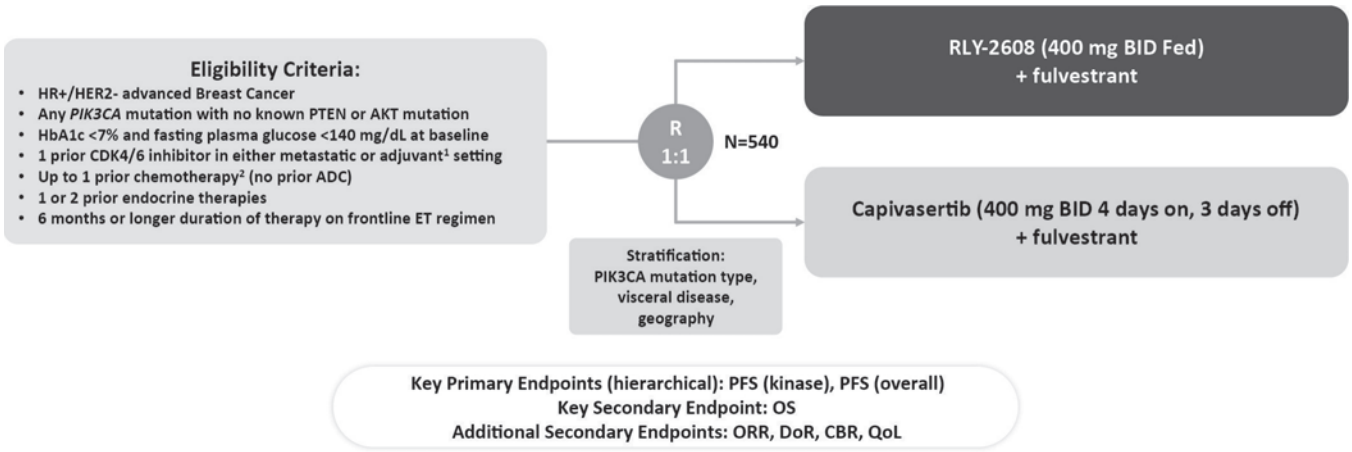
Figure 2: ReDiscover Trial design.



CCOC = clear cell ovarian cancer

We have also initiated the ReDiscover-2 Trial, which is designed to evaluate the safety and efficacy of zovegalisib plus fulvestrant in PI3Kα-mutated, HR+/HER2- advanced breast cancer patients previously treated with a CDK4/6 inhibitor in either the adjuvant or metastatic setting (n=540). The comparator arm in the ReDiscover-2 Trial is capivasertib plus fulvestrant. The ReDiscover-2 Trial is a randomized, open-label, multicenter clinical trial (**Figure 3**). The Phase 3 dose in the ReDiscover-2 Trial is 400 mg twice daily fed. A positive food effect has been observed when zovegalisib was administered to patients in the fed state, which increased the exposure level of zovegalisib compared to the fasted state. The 400 mg twice daily fed dose has been shown to achieve exposures similar to the 600 mg twice daily fasted dose, which was the dose used in the ReDiscover Trial expansion cohorts for which we have reported the interim clinical data described below.

Figure 3: Phase 3 ReDiscover-2 Trial.



1. Disease progression during or within 1 year of completing adjuvant therapy; 2. Applies to chemotherapy administered in the advanced setting.

In February 2026, we announced that the FDA granted Breakthrough Therapy designation to zovegalisib in combination with fulvestrant for the treatment of adults with PIK3CA mutant HR+/HER2- locally advanced or metastatic breast cancer following recurrence or progression on or after treatment with a CDK4/6 inhibitor.

Interim Clinical Data

In June 2025, we announced updated interim clinical data for the zovegalisib plus fulvestrant arm of the ReDiscover Trial with a data cut-off date of March 26, 2025, or the June 2025 Data, and in December 2025, we announced a subset analysis of interim clinical data for zovegalisib with a data cut-off date of October 15, 2025, or the December 2025 Data.

We presented the June 2025 Data at the American Society of Clinical Oncology 2025 Annual Meeting. As of the March 26, 2025 data cut-off date, the zovegalisib and fulvestrant combination arm of the study had enrolled 118 patients with PI3Kα-mutated, HR+, HER2- locally advanced or metastatic breast cancer across all doses in both the dose escalation and dose expansion portions of the study, including 64 patients at 600 mg twice daily, or BID, administered in the fasted state, which reaches exposures comparable to our Phase 3 dose. Among these 64 patients, 31 had a kinase mutation and 33 had a non-kinase mutation. Twelve patients also had a PTEN or AKT co-mutation and were therefore excluded from the efficacy analysis, consistent with the planned pivotal population. All patients in the zovegalisib and fulvestrant combination arm across doses had received a significant level of prior therapy in the advanced setting, including at least one prior endocrine therapy and at least one prior CDK4/6 inhibitor. Among the 64 patients who received the 600 mg BID fasted dose, 44% of patients (n=28) had received two or more prior lines of therapy.

Among the 52 patients in the zovegalisib and fulvestrant combination arm who received the 600 mg BID fasted dose and did not have a PTEN or AKT co-mutation, as of the March 26, 2025 data cut-off date:

- The median follow-up was 12.5 months;
- The median progression free survival, or PFS, was 10.3 months for all patients and 11 months for second line, or 2L, patients;
    - For 2L patients, median PFS was 18.4 months for patients with kinase mutations and 8.5 months for patients with non-kinase mutations;
- Clinical benefit rate, or CBR, was 67% across all patients (35 of 52 CBR-evaluable patients; CBR defined as the proportion of patients with complete response, partial response or stable disease for at least 24 weeks);
- Among the 31 patients with measurable disease, 12 achieved a partial response, or PR (39% confirmed objective response rate, or ORR);
    - 81% of patients experienced tumor reductions (25/31);

- Among the 15 patients with measurable disease who had a kinase mutation, two thirds achieved a PR (67% confirmed ORR; n=10); and

- Among the 15 patients who had received prior fulvestrant, 6 achieved a PR (40% confirmed ORR).

Zovegalisib in combination with fulvestrant was generally well tolerated in the 118 patients treated across all doses as of the March 26, 2025 data cut-off date. The overall tolerability profile consisted of mostly low-grade treatment-related adverse events, or TRAEs, that were manageable and reversible. Safety outcomes were generally as expected across dose levels based on exposure and consistent with mutant-selective PI3Kα inhibition. Among the 64 patients who received the 600 mg BID fasted dose, as of the March 26, 2025 data cut-off date:

- The low rate of TRAE-related dose modifications allowed for 92% median dose intensity;

- Only two patients discontinued treatment due to TRAEs (Grade 1 pruritis; Grade 1 nausea, loss of appetite);

- The majority of hyperglycemia was Grade 1; only two patients (3%) experienced Grade 3 hyperglycemia; no Grade 4-5 hyperglycemia; and

- Only 36% of patients experienced a Grade 3 TRAE; no Grade 4-5 TRAEs.

We presented the December 2025 Data at the San Antonio Breast Cancer Symposium 2025, which consisted of an efficacy subset analysis. As of the October 15, 2025 data cut-off date, among the 64 patients who received the 600 mg BID fasted dose, 45% of patients (n=29) had received two or more prior lines of therapy, 52% of patients (n=33) had received prior selective estrogen receptor degrader, or SERD, (includes fulvestrant or oral SERD), and 29% of patients (n=18) had detectable ESR1 mutations at baseline.

The total efficacy population for the December 2025 Data consisted of 52 zovegalisib and fulvestrant patients who received the 600 mg BID fasted dose and did not have a PTEN or AKT co-mutation. Median follow-up was 20.2 months as of the October 15, 2025 data cut-off date. The median PFS was 10.3 months for all patients. Among the total of 31 patients with measurable disease, ORR was 39%. For 2L patients, median PFS was 11.4 months and ORR was 47%. Efficacy was generally consistent across other subsets of patients. As of the October 15, 2025 data cut-off date, for patients who received prior SERD, median PFS was 11.4 months and ORR was 44% (7/16), and for patients who had a detectable ESR1 mutation at baseline, median PFS was 8.8 months and ORR was 60% (6/10).

As of the October 15, 2025 data cut-off date, the overall tolerability profile remained consistent with the June 2025 Data, with TRAEs that were mostly low-grade, manageable and reversible.

We believe that while the clinical data from the ReDiscover Trial disclosed to date are preliminary, the data suggest differentiated interim efficacy signals in the specified patient population and support selective target engagement across doses and mutation types with an encouraging interim safety and tolerability profile.

Vascular Anomalies

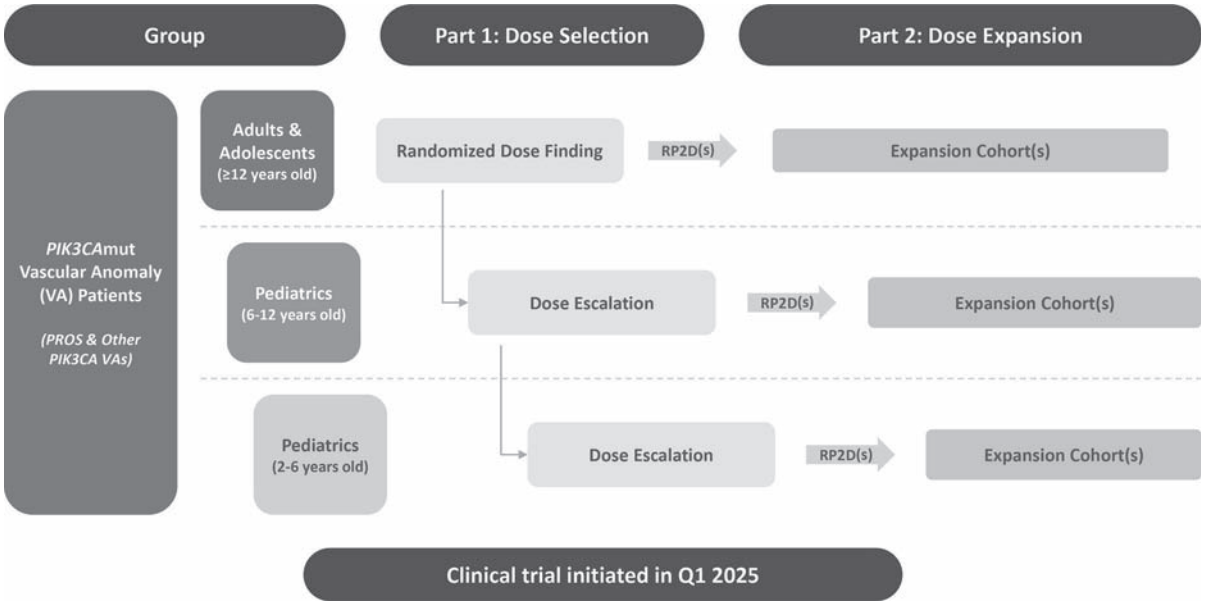
Vascular anomalies are a series of rare diseases that occur due to atypical development of lymphatic and/or blood vessels, which enlarge or form tangles, pockets or shunting vessels that cause abnormal blood flow. They can occur in different parts of the body, vary in severity and may cause symptoms such as pain, swelling, skin discoloration, limb asymmetry and functional limits. The anomalies typically grow over time, and, depending on what vessel(s) are involved, can become life-threatening. The primary vessel(s) involved determine the sub-type of anomaly, which can include venous malformations, cerebral cavernous malformations, lymphatic malformations and PIK3CA-related overgrowth spectrum.

PI3Kα is the most common driver mutation among these sub-types, causing an estimated 30-55% of these vascular anomalies. In the U.S., an estimated 170,000 people have one of these sub-types driven by a PI3Kα mutation. A mutant selective PI3Kα inhibitor provides the opportunity for greater target coverage, leading to the potential for improved efficacy and better chronic tolerability.

Clinical Development

In the first quarter of 2025, we initiated the ReInspire Trial, which is a global Phase 1/2 clinical trial designed to evaluate the safety and efficacy of zovegalisib in adults and children with PROS and anomalies driven by PIK3CA mutation (**Figure 4**). The ReInspire Trial is a three-part trial consisting of a dose selection (part 1), a basket design with exploratory single-arm cohorts for various subpopulations of participants (part 2) and a randomized, double-blinded study vs. placebo (part 3).

Figure 4: Initial development plan for Part 1 and 2 of the ReInspire Trial.



Other Pipeline Programs

In addition to our lead product candidate, we are advancing additional programs across both precision oncology and genetic diseases. We are progressing our NRAS-selective inhibitor, RLY-8161, to address NRAS-mutated solid tumors as well as our non-inhibitory chaperone for Fabry disease. We are also advancing early-stage discovery programs across both precision oncology and genetic diseases. Our precision oncology programs leverage insights into protein conformational dynamics to address high-value, genetically validated oncogenes that previously have been intractable to, or inadequately addressed by, conventional drug-discovery approaches. With respect to our genetic disease programs, we are working to address genetically validated targets in monogenic diseases where genetic alterations lead to disease-causing defects in protein conformational dynamics.

NRAS-selective inhibitor (RLY-8161)

NRAS is a known oncogene driver that belongs to the RAS family of signaling proteins. It plays an important role in cell division, cell differentiation and programmed cell death. The NRAS protein is responsible for converting GTP to GDP and is turned "on" when it binds to GTP and "off" once the GTP is converted to GDP. When mutated, the NRAS gene creates NRAS proteins that are always "on", which makes cells grow and divide uncontrollably and can lead to a number of cancers, including melanoma, colorectal and non-small-cell lung. In the U.S., an estimated 29,000 people are diagnosed each year with mutated NRAS solid tumors.

Existing approved and in-development treatments either target all RAS proteins (pan-RAS) or target other downstream parts of the pathway such as RAF and MEK, which can lead to significant off-target toxicity and limits efficacy. We have created what we believe to be the first NRAS-selective inhibitor, RLY-8161, which has been designed to address the liabilities of current pan-RAS inhibitors by only binding to NRAS, while sparing KRAS and HRAS.

Fabry disease

In Fabry disease, a defective gene, or GLA, prohibits the body from producing enough healthy versions of an enzyme called alpha-galactosidase A, or αGal, which is responsible for breaking down globotriaosylceramide, or Gb3, a fat-like substance. As a result, harmful levels of Gb3 accumulate in blood cells and tissues throughout the body, which can lead to a range of symptoms, including potentially life-threatening ones such as kidney failure, heart failure and stroke. In the U.S., approximately 10,000 people are estimated to have this rare, progressive genetic disorder.

We have created what we believe to be the first investigational non-inhibitory chaperone for Fabry disease, which is designed to stabilize the αGal protein without inhibiting its activity, thus enabling greater Gb3 clearance across organs. A non-inhibitory chaperone could potentially serve as a chronic treatment option for people with Fabry disease, either as a monotherapy or in combination with enzyme replacement therapy.

Discovery Programs

We are deploying our Dynamo platform to advance discovery stage programs across both precision oncology and genetic diseases. As with preclinical and clinical programs described above, our discovery programs leverage insights into protein conformational dynamics to address high-value, genetically validated disease-causing genes that previously have been intractable to, or inadequately addressed by, conventional drug-discovery approaches.

Our Partnered Program

Lirafugratinib

In December 2024, we entered into the Elevar Agreement with Elevar, pursuant to which Elevar was granted global development and commercialization rights for lirafugratinib, a potent, selective and oral small molecule inhibitor of FGFR2, a receptor tyrosine kinase that is frequently altered in certain cancers. Under the terms of the Elevar Agreement, Elevar assumed full responsibility for all further development activities, including submission of any new drug applications, or NDAs, all subsequent clinical development, and global commercialization for FGFR2-driven cholangiocarcinoma, or CCA and FGFR2-altered other solid tumors.

Competition

The biotechnology and pharmaceutical industries are characterized by rapid innovation of new technologies, fierce competition and strong defense of intellectual property. While we believe that our platform and our knowledge, experience and scientific resources provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others.

We compete in the segments of the pharmaceutical, biotechnology, and other related markets that address experimentally and computationally driven structure-based drug design in cancer and genetic diseases. There are other companies focusing on structure-based drug design to develop therapies in the fields of cancer and other diseases. These companies include divisions of large pharmaceutical companies and biotechnology companies of various sizes. Any product candidates that we successfully develop and commercialize will compete with currently approved therapies and new therapies that may become available in the future from segments of the pharmaceutical, biotechnology and other related markets that pursue precision medicines. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products.

We believe principal competitive factors to our business include, among other things, the rich protein structural data sets we are able to generate, the power and accuracy of our computations and predictions, ability to integrate experimental and computational capabilities, ability to successfully transition research programs into clinical development, ability to raise capital, and the scalability of the platform, pipeline, and business.

While there are many pharmaceutical and biotechnology companies that use some of the same tools that we use in our platform, we believe we compete favorably on the basis of these factors. The effort and investment required to develop a highly integrated experimental and computational platform similar to ours will hinder new entrants that are unable to invest the necessary capital and time and lack the breadth and depth of technical expertise required to develop competing capabilities.

Our competitors may obtain regulatory approval of their products more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products.

In addition, we will need to develop our product candidates in collaboration with diagnostic companies, and we will face competition from other companies in establishing these collaborations. Our competitors will also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Furthermore, we also face competition more broadly across the market for cost-effective and reimbursable treatments for cancer and genetic disease. The most common methods of treating patients with cancer are surgery, radiation and drug therapy, including chemotherapy, hormone therapy and targeted drug therapy or a combination of such methods. Similarly, there are a variety of available treatments for genetic diseases, like Fabry disease, which include enzyme replacement therapy, gene therapy, and oral targeted therapy. In many cases, these drugs are administered in combination to enhance efficacy. While our product candidates, if any are approved, may compete with these existing drug and other therapies, to the extent they are ultimately used in combination with or as an adjunct to these therapies, our product candidates may not be competitive with them. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded products. We expect that if any of our product candidates are approved, they will be priced at a significant premium over competitive generic, including branded generic, products. As a result, obtaining market acceptance of, and gaining significant share of the market for, any of our product candidates that we successfully introduce to the market will pose challenges. In addition, many companies

are developing new therapeutics, and we cannot predict what the standard of care will be as our product candidates progress through clinical development.

Zovegalisib– Breast Cancer and Solid Tumors

We expect that zovegalisib will compete against approved medicines, Piqray (alpelisib), a non-selective PI3Kα inhibitor marketed by Novartis for the treatment of PIK3CA mutated HR+, HER2- advanced or metastatic breast cancer, Truqap (capivasertib), an AKT inhibitor marketed by AstraZeneca for the treatment of metastatic breast cancer with a PIK3CA, AKT1 or PTEN alteration, and Itovebi (inavolisib), a non-selective PI3Kα inhibitor marketed by Roche Holding AG through its subsidiary Genentech for the treatment of PIK3CA mutated HR+, HER2- advanced or metastatic breast cancer. We are aware of other companies developing therapeutics that target both wild-type and mutant PI3Kα, including, but not limited to, Celcuity Inc and Totus Medicines. In addition, Eli Lilly and Company and OnKure have clinical development programs for mutant-selective PI3Kα inhibitors.

Zovegalisib– Vascular Anomalies

We expect that zovegalisib will compete against the only approved systemic therapy medicine, Vijoice (alpelisib), a non-selective PI3Kα inhibitor marketed by Novartis for the treatment of PIK3CA-Related Overgrowth Spectrum (PROS), available under accelerated approval. There are no approved agents for any other vascular anomaly sub-types. We are aware of other companies developing therapies for vascular anomalies, including Kaken Pharmaceutical Company, which is developing an oral non-selective PI3Kα inhibitor for patients with refractory vascular anomalies, and Palvella Therapeutics, which is developing a topical mTOR inhibitor for patients with cutaneous manifestations of lymphatic and venous malformations.

NRAS-Selective Inhibitor (RLY-8161)

While there are currently no approved products that selectively target NRAS, there are therapeutic approaches that target other nodes in the RAS/MAPK pathway which we'd expect our NRAS-selective molecule to compete against. This includes pan-RAF and MEK inhibitors, which are often used in combination, such as Braftovi (encorafenib), a BRAF inhibitor indicated for use in combination with Mektovi (binimetinib), a MEK inhibitor, both marketed by Pfizer for the treatment of metastatic melanoma with a BRAF V600E or V600K mutation. Braftovi as a single agent is additionally recommended for use in certain cases of cutaneous melanoma by the National Comprehensive Cancer Network, though has not received regulatory approval. There are also clinical stage pan-RAS molecules in development, including Revolution Medicines RMC-6236.

Fabry Disease

We expect our non-inhibitory chaperone for Fabry disease to compete against Galafold (migalastat), an αGal chaperone marketed by Amicus Therapeutics for the treatment of Fabry disease with an amenable galactosidase alpha gene variant, as well as approved enzyme replacement therapies for Fabry disease including Fabrazyme (agalsidase beta), marketed by Sanofi, Replagal (agalsidase alfa), marketed by Takeda, and Elfabrio (pegunigalsidase alfa-iwxj), marketed by Protalix Biotherapeutics.

Our Collaborations

License Agreements and Strategic Collaborations

Collaboration and License Agreement with D. E. Shaw Research, LLC

On August 17, 2016, we entered into a Collaboration and License Agreement with D. E. Shaw Research, which was amended to extend the term and otherwise modify certain of the provisions thereof. We refer to this agreement, as amended and restated from time to time, as the DESRES Agreement. Under the DESRES Agreement, we agreed to collaborate with D. E. Shaw Research to research certain biological targets using computational modeling with an aim to develop and commercialize compounds and products directed to such targets. D. E. Shaw Research has no involvement with the clinical development or potential commercialization of these compounds and products, regardless of any co-ownership rights pursuant to the terms of the DESRES Agreement, and instead receives solely milestone and royalty payments as described below. The initial research term under the DESRES Agreement ended on August 16, 2025, and we are not currently collaborating with D.E. Shaw Research on any of our active preclinical programs.

Under the DESRES Agreement, Category 1 Targets are targets that, among other things, we collaborated, or intended to collaborate, on with D. E. Shaw Research, D. E. Shaw Research has exclusivity obligations with respect to, and we may owe royalties and other milestone payments on. The targets associated with all of our current programs in clinical development are Category 1 Targets under the DESRES Agreement.

Work product that we jointly developed with D. E. Shaw Research was initially co-owned with them. We have the right to have patents claiming certain product candidates assigned to us upon issuance of those patents. For each Category 1 Target, there is a limit to the number of core compounds and total compounds, including derivatives of core compounds, that can be designated as solely owned by us,

subject to certain adjustments. Each of we and D. E. Shaw Research grants to the other a perpetual, irrevocable, non-exclusive license for jointly held intellectual property, subject to certain exclusions.

During the initial research term, D. E. Shaw Research was restricted from researching any Category 1 Target (or granting certain rights with respect to such target) with the aim of pursuing any compound designed to interact with or bind to such Category 1 Target, subject to some exceptions. Following the end of the initial research term, D. E. Shaw Research is similarly restricted with respect to any target that was a Category 1 Target at the end of the initial research term, subject to some exceptions. However, D. E. Shaw Research is not bound by such exclusivity provisions with respect to a particular Category 1 Target if we, and parties acting on our behalf, stop using commercially reasonable efforts to research, develop or commercialize any products against such Category 1 Target. Further, D. E. Shaw Research will be released from such exclusivity obligations with respect to a particular Category 1 Target if, at least 24 months after the end of the initial research term, D. E. Shaw Research informs us that D. E. Shaw Research will forgo all future payments with respect to such Category 1 Target.

Through December 31, 2025, we have made cash payments to D. E. Shaw Research totaling $57.1 million in the aggregate. On a product-by-product basis, we have also agreed to pay D. E. Shaw Research milestone payments upon the achievement of certain development and regulatory milestone events for products we develop under the DESRES Agreement that are directed to a Category 1 Target or any target that was a Category 1 Target. Our PI3K, FGFR2, and NRAS programs are each directed to Category 1 Targets. Such payments for achievement of development and regulatory milestones total up to $7.3 million in the aggregate for each of the first three products we develop, and up to $6.3 million in the aggregate for each product we develop after the first three.

Additionally, we have agreed to pay D. E. Shaw Research, on a product-by-product basis, with respect to products directed to Category 1 Targets or any target that was a Category 1 Target, royalties in the low single digits on worldwide net sales of products that we commercialize directed to the targets selected for development under the DESRES Agreement, subject to certain reductions. Royalties are payable on a product-by-product and country-by-country basis until the later of twelve years after first commercial sale in such country or the expiration of all applicable regulatory exclusivities in such country. On a product-by-product basis, we also agreed to pay D. E. Shaw Research sales milestone payments up to $36.0 million in the aggregate based on sales of each product directed to a Category 1 Target or any target that was a Category 1 Target. Further, if we enter into transactions granting third parties rights to a Category 1 Target or a compound or product directed to a Category 1 Target or any target that was a Category 1 Target such as our licensing arrangement with Elevar for lirafugratinib discussed below, but subject to certain exclusions, we will share with D. E. Shaw Research a percentage of the proceeds of such transactions ranging from the low- to high-single digits, depending on the stage of development of compounds or products directed to such target at the time we enter into such transaction. We also paid an annual collaboration fee during the initial research term.

Unless earlier terminated, the DESRES Agreement will continue on a target-by-target basis until all payment obligations have expired. D. E. Shaw Research has the right to terminate the DESRES Agreement due to non-payment. We and D. E. Shaw Research each have the right to terminate the DESRES Agreement due to an uncured material breach by the other party, or in the event the other party becomes insolvent or enters into bankruptcy or dissolution proceedings. Our payment obligations to D. E. Shaw Research survive termination of the DESRES Agreement. If D. E. Shaw Research terminates the DESRES Agreement, the exclusivity obligations will terminate. If we terminate the DESRES Agreement, D. E. Shaw Research remains bound by its exclusivity obligations with respect to certain targets until, on a target-by-target basis, there are no further payment obligations due to D. E. Shaw Research in respect of such targets.

Exclusive Global Licensing Agreement with Elevar

On December 2, 2024, we entered into the Elevar Agreement. Pursuant to the Elevar Agreement, Elevar was granted global development and commercialization rights for lirafugratinib. Elevar is responsible for all further development activities and global commercialization for lirafugratinib in FGFR2-driven CCA and FGFR2-altered other solid tumors.

Collaboration and License Agreement with Genentech

On December 11, 2020, we entered into a Collaboration and License Agreement with Genentech, Inc. and F. Hoffmann-La Roche Ltd, collectively referred to as Genentech, which was amended on February 2, 2022, to modify certain terms thereof. We refer to this agreement, as amended from time to time, as the Genentech Agreement. Pursuant to the Genentech Agreement, we and Genentech collaborated on the development and commercialization of RLY-1971, our inhibitor of SRC homology region 2 domain containing phosphatase 2 (now referred to as migoprotafib, or GDC-1971), or the Genentech Agreement.

Under the terms of the Genentech Agreement, we received $75.0 million in an upfront payment in 2021, as well as $45.0 million in milestone payments from Genentech as of December 31, 2025. Genentech elected to terminate the Genentech Agreement without cause, effective as of January 7, 2025. As a result of the termination of the Genentech Agreement, the parties no longer have any development or commercialization obligations and the licenses that we granted to Genentech pursuant to the Genentech Agreement ceased to be in effect. As of the termination date, we are no longer entitled to receive any further milestones or other payments under the Genentech Agreement. We will not continue development of migoprotafib.

Other Collaborations

While we have invested extensively in our in-house capabilities and know-how, we selectively work with key collaborators and field experts on certain emerging experimental and computational tools and techniques we use in our drug discovery process.

In June 2024, we entered into a global clinical trial collaboration with Pfizer for the development of zovegalisib in combination with fulvestrant and atirmociclib, Pfizer's investigative selective-CDK4 inhibitor, in patients with PI3Kα-mutated, HR+, HER2- metastatic breast cancer.

Intellectual Property

We seek to protect the intellectual property and proprietary technology that we consider important to our business, including by pursuing patent applications that cover our product candidates and methods of using the same, as well as any other relevant inventions and improvements that we believe to be commercially important to the development of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position. Our commercial success depends, in part, on our ability to obtain, maintain, enforce and protect our intellectual property and other proprietary rights for the technology, inventions and improvements we consider important to our business, and to defend any patents we may own or in-license in the future, prevent others from infringing any patents we may own or in-license in the future, preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating or otherwise violating the valid and enforceable patents and proprietary rights of third parties.

As with other biotechnology and pharmaceutical companies, our ability to maintain and solidify our proprietary and intellectual property position for our product candidates and technologies will depend on our success in obtaining effective patent claims and enforcing those claims if granted. However, our pending provisional and PCT patent applications, and any patent applications that we may in the future file or license from third parties, may not result in the issuance of patents and any issued patents we may obtain do not guarantee us the right to practice our technology or commercialize our product candidates. We also cannot predict the breadth of claims that may be allowed or enforced in any patents we may own or in-license in the future. Any issued patents that we currently own or may own or in-license in the future may be challenged, invalidated, circumvented or have the scope of their claims narrowed. In addition, because of the extensive time required for clinical development and regulatory review of a product candidate we may develop, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby limiting the protection such patent would afford the respective product and any competitive advantage such patent may provide.

The term of individual patents depends upon the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. In most countries, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the United States, a patent’s term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office, or USPTO, in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier expiring patent. The term of a patent claiming a new drug product may also be eligible for a limited patent term extension when FDA approval is granted, provided statutory and regulatory requirements are met. The restoration period granted on a patent covering a product is typically one-half the time between the effective date of a clinical investigation involving human beings is begun and the submission date of an application, plus the time between the submission date of an application and the ultimate approval date. The restoration period cannot be longer than five years, and the restoration period may not extend the patent term beyond 14 years from the date of FDA approval. Only one patent applicable to an approved product is eligible for the extension, and only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended. Additionally, the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension or restoration in consultation with the FDA. In the future, if our product candidates receive approval by the FDA, we expect to apply for patent term extensions on one issued patent covering each of those products, depending upon the length of the clinical studies for each product and other factors. There can be no assurance that patents will issue from our current or future pending patent applications, or that we will benefit from any patent term extension or favorable adjustments to the terms of any patents we may own or in-license in the future. In addition, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. The patent term may be inadequate to protect our competitive position on our products for an adequate amount of time.

Zovegalisib

As of December 31, 2025, we co-owned with D.E. Shaw Research pending U.S. and foreign patent applications, covering our lead PI3K program, which are directed to the composition of matter for the drug candidates of the program, including zovegalisib, analogs thereof, as well as methods of making and using these compounds. Any U.S. or foreign patents that may issue from this patent family, if granted and all appropriate maintenance fees paid, would be scheduled to expire in 2041, excluding any additional term for patent term adjustment or patent term extension, if applicable. As of the date of this Annual Report on Form 10-K, we co-own with D.E. Shaw Research granted patents in Eurasia, Japan, Korea, Chile, and the United States covering the composition of matter of zovegalisib.

As of December 31, 2025, we wholly owned pending U.S. and foreign patent applications relating to zovegalisib isotopolog composition of matter, methods of treatment, solid forms and methods of manufacture. Any U.S. or foreign patents that may issue from this patent family, if granted and all appropriate maintenance fees paid, would be scheduled to expire in 2042, excluding any additional term for patent term adjustment or patent term extension, if applicable.

Lirafugratinib

As of December 31, 2025, we co-owned with D. E. Shaw Research pending U.S. and foreign patent applications which relate to our FGFR2 inhibitors. Any U.S. or foreign patents that may issue from this patent family, if granted and all appropriate maintenance fees paid, would be scheduled to expire in 2040, excluding any additional term for patent term adjustment or patent term extension, if applicable. As of the date of this Annual Report on Form 10-K, we own granted patents in Eurasia, Europe, Taiwan, Japan, Hong Kong, and the United States covering the composition of matter of lirafugratinib.

As of December 31, 2025, we wholly owned pending U.S. and foreign patent applications relating to lirafugratinib salts composition of matter, methods of treatment, solid forms and methods of manufacture. Any U.S. or foreign patents that may issue from this patent family, if granted and all appropriate maintenance fees paid, would be scheduled to expire in 2041, excluding any additional term for patent term adjustment or patent term extension, if applicable. As of the date of this Annual Report on Form 10-K, we own a granted patent in the United States covering solid forms of lirafugratinib.

As of December 31, 2025, Elevar Therapeutics, as the exclusive licensee of our FGFR2 inhibitor program, has the sole right and responsibility for the prosecution, maintenance, and enforcement of all of our solely-owned and jointly-owned (with D.E. Shaw Research) patents and patent applications directed to our FGFR2 inhibitor program. We retain certain reversion rights in the event Elevar terminates its license, or declines to prosecute claims specifically relating to lirafugratinib.

Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the USPTO or other foreign jurisdiction are often significantly narrowed by the time they issue, if they issue at all. Any U.S. or foreign patent issuing from these provisional, PCT, or foreign patent applications (assuming they are timely converted into non-provisional applications, and such non-provisional applications are granted as issued patents) would be scheduled to expire twenty years from their earliest non-provisional priority filing date, excluding any additional term for patent term adjustment or patent term extension, and assuming national phase entries are timely made based upon the pending PCT application, and payment of all applicable maintenance or annuity fees. Any of our pending PCT patent applications are not eligible to become issued patents until, among other things, we file national stage patent applications within 30 months in the countries in which we seek patent protection. If we do not timely file any national stage patent applications, we may lose our priority date with respect to our PCT patent applications and any patent protection on the inventions disclosed in such PCT patent applications. Our provisional patent applications may never result in issued patents and are not eligible to become issued patents until, among other things, we file a non-provisional patent application and/or PCT patent application within 12 months of filing the related provisional patent application. If we do not timely file non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. While we intend to timely file non-provisional and national stage patent applications relating to our provisional and PCT patent applications, we cannot predict whether any of our current or future patent applications for any of our product candidates or technology, will issue as patents. If we do not successfully obtain patent protection, or, even if we do obtain patent protection, if the scope of the patent protection we, Genentech, or our potential licensors, obtain with respect to any of our product candidates or technology is not sufficiently broad, we will be unable to prevent others from using our technology or from developing or commercializing technology and products similar or identical to ours or other competing products and technologies.

In addition to patent applications, we rely on unpatented trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and confidential know-how are difficult to protect. In particular, we anticipate that with respect to the building of our compound library, our trade secrets and know-how will over time be disseminated within the industry through independent development and public presentations describing the methodology. We seek to protect our proprietary information, in part, by executing confidentiality agreements with our collaborators and scientific advisors and non-competition, non-solicitation, confidentiality and invention assignment agreements with our employees and consultants. We have also executed agreements requiring assignment of inventions with selected consultants, scientific advisors and collaborators. The confidentiality agreements we enter into are designed to protect our proprietary information and the agreements or clauses requiring assignment of inventions to us are designed to grant us ownership of technologies that are developed through our relationship with the respective counterparty. We cannot guarantee that we will have executed such agreements with all applicable employees and contractors, or that these agreements will afford us adequate protection of our intellectual property and proprietary information rights. In addition, our trade secrets and/or confidential know-how may become known or be independently developed by a third party or misused by any collaborator to whom we disclose such information. These agreements may also be breached, and we may not have an adequate remedy for any such breach. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain or use information that we regard as proprietary. Although we take steps to protect our proprietary information, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information. For more information regarding the risks related to our intellectual property, please see "Risk Factors—Risks Related to our Intellectual Property."

Commercialization

Subject to receiving marketing approvals, we expect to commence commercialization activities by building a focused sales and marketing organization in the United States to sell our products. We believe that such an organization will be able to address the community of oncologists and genetic disease specialists who are the key specialists in treating the patient populations for which our product candidates are being developed. Outside the United States, we expect to enter into distribution and other marketing arrangements with third parties for any of our product candidates that obtain marketing approval.

We also plan to build a marketing and sales management organization to create and implement marketing strategies for any products that we market through our own sales organization and to oversee and support our sales force. The responsibilities of the marketing organization would include developing educational initiatives with respect to approved products and establishing relationships with researchers and practitioners in relevant fields of medicine.

Manufacturing

We do not have any manufacturing facilities or personnel. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates undergoing preclinical testing, as well as for clinical testing and commercial manufacture if our product candidates receive marketing approval.

All of our drug candidates are small molecules and are manufactured in synthetic processes from available or custom-made starting materials. The chemistry appears amenable to scale-up and we rely on the specialized equipment of third parties to manufacture our product candidates. We expect to continue to develop product candidates that can be produced cost-effectively at contract manufacturing facilities.

We generally expect to rely on third parties for the manufacture of companion diagnostics for our products, which are assays or tests to identify an appropriate patient population. Depending on the technology solutions we choose, we may rely on multiple third parties to manufacture and sell a single test.

Governmental Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, recordkeeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs. We, along with our vendors, contract research organizations, or CROs, and contract manufacturers, are and will be required to navigate the various preclinical, clinical, manufacturing and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of our product candidates. The process of obtaining regulatory approvals of drugs and ensuring subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

In the United States, where we are initially focusing our drug development, the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act, or FD&C Act, as amended, its implementing regulations and other laws. If we fail to comply with applicable FDA or other requirements at any time with respect to product development, clinical testing, approval or any other legal requirements relating to product manufacture, processing, handling, storage, quality control, safety, marketing, advertising, promotion, packaging, labeling, export, import, distribution, or sale, we may become subject to administrative or judicial sanctions or other legal consequences. These sanctions or consequences could include, among other things, the FDA's refusal to approve pending applications, issuance of clinical holds for ongoing studies, suspension or revocation of approved applications, warning or untitled letters, product withdrawals or recalls, product seizures, relabeling or repackaging, total or partial suspensions of manufacturing or distribution, injunctions, fines, civil penalties or criminal prosecution.

The process required by the FDA before our product candidates are approved as drugs for therapeutic indications and may be marketed in the United States generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice, or GLP, requirements;
- completion of the manufacture, under current Good Manufacturing Practices, or cGMP, conditions, of the drug substance and drug product that the sponsor intends to use in human clinical trials along with required analytical and stability testing;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical trials may begin;
- approval by an institutional review board, or IRB, or independent ethics committee at each clinical trial site before each trial may be initiated;

- performance of adequate and well-controlled clinical trials in accordance with applicable IND regulations, good clinical practice, or GCP, requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;

- submission to the FDA of a New Drug Application, or an NDA;

- a determination by the FDA within 60 days of its receipt of an NDA, to accept the filing for review;

- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the drug will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;

- potentially, satisfactory completion of FDA audit of the clinical trial sites that generated the data in support of the NDA;

- payment of user fees for FDA review of the NDA; and

- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the United States.

Preclinical studies and clinical trials for drugs

Before testing any drug in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluations of drug chemistry, formulation and stability, as well as *in vitro* and animal studies to assess safety and in some cases to establish the rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulation, including GLP requirements for safety/toxicology studies. The results of the preclinical studies, together with manufacturing information and analytical data, must be submitted to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before clinical trials may begin. Some long-term preclinical testing may continue after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, and imposes a full or partial clinical hold. The FDA must notify the trial sponsor of the grounds for the hold and any identified deficiencies must be resolved before the clinical trial can begin. Submission of an IND may result in the FDA not allowing clinical trials to commence or not allowing clinical trials to commence on the terms originally specified in the IND. A clinical hold can also be imposed once a trial has already begun, thereby halting the trial until the deficiencies articulated by the FDA are corrected.

The clinical stage of development involves the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, who generally are physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirements that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters and criteria to be used in monitoring safety and evaluating effectiveness. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable compared to the anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. The FDA, the IRB, or the trial sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trials to public registries. Information about clinical trials, including results for clinical trials other than Phase 1 investigations, must be submitted within specific timeframes for publication on www.ClinicalTrials.gov, a clinical trials database maintained by the National Institutes of Health, or NIH. Information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Although sponsors are obligated to disclose the results of their clinical trials after completion, disclosure of the results can be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to public notification of noncompliance, civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the FDA will nevertheless accept the results of the study in support of an NDA if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

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

- *Phase 1*—Phase 1 clinical trials involve initial introduction of the investigational product into healthy human volunteers or patients with the target disease or condition. These studies are typically designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, excretion the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.

- *Phase 2*—Phase 2 clinical trials typically involve administration of the investigational product to a limited patient population with a specified disease or condition to evaluate the drug's potential efficacy, to determine the optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks.

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

In March 2022, the FDA released a final guidance entitled "Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics," which outlines how drug developers can utilize an adaptive trial design commonly referred to as a seamless trial design in early stages of oncology drug development (i.e., the first-in-human clinical trial) to compress the traditional three phases of trials into one continuous trial called an expansion cohort trial. Information to support the design of individual expansion cohorts are included in IND applications and assessed by the FDA. Expansion cohort trials can potentially bring efficiency to drug development and reduce development costs and time.

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

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA. Written IND safety reports must be submitted to the FDA and the investigators fifteen days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human volunteers and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information.

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

U.S. marketing approval for drugs

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

The FDA reviews all submitted NDAs before it accepts them for filing and may request additional information rather than accepting the NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the NDA. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective for the indications sought and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity. Under the goals and polices agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA targets ten

months, from the filing date, in which to complete its initial review of a new molecular entity NDA and respond to the applicant, and six months from the filing date of a new molecular entity NDA for priority review. The FDA does not always meet its PDUFA goal dates for standard or priority NDAs, and the review process is often extended by FDA requests for additional information or clarification.

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

The FDA also may require submission of a Risk Evaluation and Mitigation Strategy, or REMS, if it believes that a risk evaluation and mitigation strategy is necessary to ensure that the benefits of the drug outweigh its risks. A REMS can include use of risk evaluation and mitigation strategies like medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk-minimization tools.

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

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

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

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

With respect to oncology products, the FDA may review applications under Real-Time Oncology Review, or RTOR, established by the FDA's Oncology Center of Excellence. RTOR, which allows an applicant to pre submit components of the application to allow the FDA to review clinical data before the complete filing is submitted, aims to explore a more efficient review process to ensure that safe and effective treatments are available to patients as early as possible, while maintaining and improving review quality. Drugs considered for review under RTOR must, among other things, be likely to demonstrate substantial improvements on a clinically relevant endpoint(s) over available therapy, and must have easily interpreted endpoints. In addition, no aspect of the application should be likely to require a longer review time, such as, for example, a requirement for a new REMS. To determine eligibility for RTOR, the FDA requires top-line efficacy and safety results from an applicant's pivotal clinical trial(s), as well as completion of database lock for the clinical trial(s). The FDA will generally make a decision regarding acceptance into RTOR within twenty (20) business days of receipt of the request from the applicant. If an applicant is not accepted into RTOR, the applicant will follow routine application submission procedures.

Orphan drug designation and exclusivity

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects 200,000 or more individuals in the United States, there is no reasonable expectation that the cost of developing and making the product available in the United States for the disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an NDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, though companies developing orphan products are eligible for certain incentives, including tax credits for qualified clinical testing and waiver of application fees.

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

Expedited development and review programs for drugs

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

A new drug is eligible for Fast Track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. Fast Track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed. Rolling review means that the agency may review portions of the marketing application before the sponsor submits the complete application. In addition, a new drug may be eligible for Breakthrough Therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug 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 drug development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any product submitted to the FDA for approval, including a product with Fast Track or Breakthrough Therapy designation, may also be eligible for additional FDA programs intended to expedite the review and approval process, including Priority Review designation and Accelerated Approval. A product is eligible for Priority Review, once an NDA or Biologics License Application is submitted, if the drug that is the subject of the marketing application has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. Under Priority Review, the FDA's goal date to take action on the marketing application is six months compared to ten months for a standard review. Products are eligible for Accelerated Approval if they can be shown to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, which is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

Accelerated Approval is usually contingent on a sponsor's agreement to conduct additional post-approval studies to verify and describe the product's clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug receiving Accelerated Approval perform adequate and well-controlled post-marketing clinical trials with due diligence and, under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA is permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted Accelerated Approval. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or an indication approved if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, for products being considered for Accelerated Approval, the FDA generally requires, unless otherwise informed by the agency, pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval do not change the scientific or medical standards for approval or the quality of evidence necessary to support approval, though they may expedite the development or review process.

Pediatric information and pediatric exclusivity

Under the Pediatric Research Equity Act, or PREA, as amended, certain NDAs and NDA supplements must contain data that can be used to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The FD&C Act requires that a sponsor who is planning to submit a marketing application for a drug

that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs. Additionally, for molecularly targeted cancer drugs, beginning after February 3, 2029, the FDA may require testing of certain novel single ingredient or combination regimens to yield clinically meaningful pediatric study data that is gathered using appropriate formulations for each age group for which the study is required, regarding dosing, safety, and preliminary efficacy to inform potential pediatric labeling.

A drug can also obtain pediatric market 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, provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining.

U.S. post-approval requirements for drugs

Drugs manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, reporting of adverse experiences with the product, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the drug, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-market testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product’s safety and effectiveness after commercialization. In addition, drug manufacturers and their subcontractors involved in the manufacture and distribution of approved drugs 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 ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements. Manufacturers and other parties involved in the drug supply chain for prescription drug products and those supplying products, ingredients, and components of them, must also comply with product tracking and tracing requirements, including electronic systems for identification and tracing, and are responsible for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. Failure to comply with statutory and regulatory requirements may subject a manufacturer to legal or regulatory action, such as warning letters, suspension of manufacturing, product seizures, injunctions, civil penalties or criminal prosecution. There is also a continuing, annual prescription drug product program user fee.

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 revisions to the approved labeling to add new safety information, requirements for post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, 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 healthcare programs; or mandated modification of promotional materials and labeling and issuance of corrective information.

From time to time, legislation is drafted, introduced, passed in Congress, and signed into law that could significantly change the statutory provisions governing the approval, manufacturing, and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations, guidance, and policies are often revised or reinterpreted by the agency in ways that may significantly affect the manner in which pharmaceutical products are regulated and marketed.

Regulation of companion diagnostics

Companion diagnostics identify patients who are most likely to benefit from a particular therapeutic product; identify patients likely to be at increased risk for serious side effects as a result of treatment with a particular therapeutic product; or monitor response to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness. Companion diagnostics are regulated as medical devices by the FDA. In the United States, the FD&C Act, 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 or FDA exercise of enforcement discretion applies, diagnostic tests generally require marketing clearance or approval from the FDA prior to commercialization. The two primary types of FDA marketing authorization applicable to a medical device are clearance of a premarket notification, or 510(k), and approval of a premarket approval application, or PMA.

To obtain 510(k) clearance for a medical device, or for certain modifications to devices that have received 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or to a pre-amendment device that was in commercial distribution before May 28, 1976, or a predicate device, for which the FDA has not yet called for the submission of a PMA. In making a determination that the device is substantially equivalent to a predicate device, the FDA compares the proposed device to the predicate device and assesses whether the subject device is comparable to the predicate device with respect to intended use, technology, design and other features which could affect safety and effectiveness. If the FDA determines that the subject device is substantially equivalent to the predicate device, the subject device may be cleared for marketing. The 510(k) premarket notification pathway generally takes from three to twelve months from the date the application is completed, but can take significantly longer.

A PMA must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. For diagnostic tests, a PMA typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the quality system regulation, or QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures. The FDA's review of an initial PMA is required by statute to take between six to ten months, although the process typically takes longer, and may require several years to complete. If the FDA evaluations of both the PMA and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny the approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. Once granted, PMA approval may be withdrawn by the FDA if compliance with post-approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing.

On July 31, 2014, the FDA issued a final guidance document addressing the development and approval process for "In Vitro Companion Diagnostic Devices." According to the guidance document, for novel therapeutic products that depend on the use of a diagnostic test and where the diagnostic device could be essential for the safe and effective use of the corresponding therapeutic product, the companion diagnostic device should be developed and approved or cleared contemporaneously with the therapeutic, although the FDA recognizes that there may be cases when contemporaneous development may not be possible. However, in cases where a drug cannot be used safely or effectively without the companion diagnostic, the FDA's guidance indicates it will generally not approve the drug without the approval or clearance of the diagnostic device. The FDA also issued a draft guidance document in July 2016 setting forth the principles for co-development of an in vitro companion diagnostic device with a therapeutic product. The draft guidance describes principles to guide the development and contemporaneous marketing authorization for the therapeutic product and its corresponding in vitro companion diagnostic.

Once cleared or approved, the companion diagnostic device must adhere to post-marketing requirements including the requirements of the FDA's QSR, adverse event reporting, recalls and corrections along with product marketing requirements and limitations. Like drug makers, companion diagnostic makers are subject to unannounced FDA inspections at any time during which the FDA will conduct an audit of the product(s) and the company's facilities for compliance with its authorities.

Other regulatory matters

Manufacturing, sales, promotion and other activities of product candidates following product approval, where applicable, or commercialization are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, which may include the Centers for Medicare & Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments and governmental agencies.

Other healthcare laws

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

Insurance coverage and reimbursement

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, the product. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, which will require additional expenditure above and beyond the costs required to obtain FDA or other comparable regulatory approvals. Additionally, companies may also need to provide discounts to purchasers, private health plans or government healthcare programs, and net prices for our products may also be reduced by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, our operations and financial condition. Additionally, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators or licensees receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Current and future healthcare reform legislation

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare. For example, in 2010, the United States Congress enacted the Affordable

Care Act, or ACA, which, among other things, includes changes to the coverage and payment for products under government health care programs. The ACA includes provisions of importance to our potential product candidates that:

- created an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products, apportioned among these entities according to their market share in certain government healthcare programs;
- expanded eligibility criteria for Medicaid programs, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program;
- expanded the types of entities eligible for the 340B drug discount program;
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide point-of-sale-discounts off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D; and
- created a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2031 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers were further reduced starting on January 1, 2025, however legislation has been introduced in the U.S. Congress that would, if enacted, reverse these payment reductions. In addition to provider payment cuts under Medicare, the American Rescue Plan Act of 2021 also eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024. These laws and regulations may result in additional reductions in Medicare and other healthcare funding available for healthcare providers and may otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

The Inflation Reduction Act of 2022, or the IRA, was signed into law in August 2022. The IRA includes several provisions that could impact our business to varying degrees, including provisions that create a $2,000 out-of-pocket cap for Medicare Part D beneficiaries, impose new manufacturer financial liability on all drugs in Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delay until January 1, 2032 the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. Although the effects of the IRA on our business and the healthcare industry in general are not yet known, we are taking into consideration the potential impact of the IRA on our development and commercialization activities.

The Creating and Restoring Equal Access to Equivalent Samples Act (CREATES Act), was enacted in 2019 requiring sponsors of approved new drug applications and biologics license applications to provide sufficient quantities of product samples on commercially reasonable, market-based terms to entities developing generic drugs and biosimilar biological products. The law establishes a private right of action allowing developers to sue application holders that refuse to sell them product samples needed to support their applications. If we are required to provide product samples or allocate additional resources to respond to such requests or any legal challenges under this law, our business could be adversely impacted.

In addition, the Trump administration has taken and is expected to take executive and administrative action to reduce prescription drug costs. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Trump administration may reverse or otherwise change these previous measures, the current administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

Outside the United States, ensuring coverage and adequate payment for a product also involves challenges. Pricing of prescription pharmaceuticals is subject to government control in many countries. Pricing negotiations with government authorities can extend well

beyond the receipt of regulatory approval for a product and may require a clinical trial that compares the cost-effectiveness of a product to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization.

In the European Union, or EU, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed upon. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the EU provides options for its Member States to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU Member States may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other Member States allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the EU have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the EU. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. 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 trade, i.e., arbitrage between low-priced and high-priced Member States, can further reduce prices. 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 products, if approved in those countries.

Compliance with other federal and state laws or requirements; changing legal requirements

If any products that we may develop are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, labeling, packaging, distribution, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws, among other requirements to which we may be subject.

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

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

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

Other U.S. environmental, health and safety laws and regulations

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

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

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

Government regulation of drugs outside of the United States

To market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization or identification of an alternate regulatory pathway, manufacturing, commercial sales and distribution of our products.

Clinical trial approval

In April 2014, the EU adopted the new Clinical Trials Regulation, (EU) No 536/2014 (Clinical Trials Regulation) which replaced the current Clinical Trials Directive 2001/20/EC on January 31, 2022. The Clinical Trials Regulation is directly applicable in all the EU Member States (meaning no national implementing legislation is required). The Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the EU. The main characteristics of the Clinical Trials Regulation include: a streamlined application procedure via a single-entry point, through the Clinical Trials Information System, or CTIS; a single set of documents to be prepared and submitted for the application, as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned). Part II is assessed separately by each Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure continues to be governed by the national law of the concerned EU Member State, however, overall related timelines are defined by the Clinical Trials Regulation.

Drug Review and Approval

In the EU, medicinal products must be authorized for marketing by using either the centralized authorization procedure or national authorization procedures.

- *Centralized authorization procedure*—If pursuing marketing authorization of a product candidate for a therapeutic indication under the centralized procedure, following the opining of the EMA's Committee for Medicinal Products for Human Use, or, CHMP, the European Commission issues a single marketing authorization valid across the EU and in the additional Member States of the European Economic Area (Iceland, Liechtenstein and Norway). The centralized procedure is compulsory for human medicines derived from biotechnology processes, advanced therapy medicinal products (i.e. gene therapy, somatic cell therapy and tissue engineered products), products that contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune diseases and other immune dysfunctions and viral diseases, and products designated as orphan medicines. For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned contains a new active substance not yet authorized in the EU, is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health in the EU. Under the centralized procedure the maximum timeframe for the evaluation of a marketing authorization application, or MAA, by the European Medicines Agency, or EMA, is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Where the CHMP gives a positive opinion, it provides the opinion together with supporting documentation to the European Commission, who makes the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is 150 days, excluding clock stops, but it is possible that the CHMP can revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

- *National authorization procedures*—There are also two other possible routes to authorize products for therapeutic indications in several countries, which are available for products that fall outside the scope of the centralized procedure:

- *Decentralized procedure*—Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure.

- *Mutual recognition procedure*—In the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following this, additional marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned recognize the validity of the original, national marketing authorization.

Periods of authorization and renewals

A marketing authorization has an initial validity for five years in principle. 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 EU Member State for a nationally

authorized product. Once subsequently definitively renewed, the marketing authorization shall be valid for an unlimited period, unless the European Commission or the national competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (in the case of the centralized procedure) or on the market of the authorizing EU Member State for a nationally authorized product within three years after authorization, ceases to be valid (the so-called sunset clause).

Drug and market exclusivity

In the EU, innovative products for therapeutic indications that are authorized for marketing (i.e., reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from referencing the innovator's 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 market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial authorization of the reference 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. There is no guarantee that a product will be considered by the EMA to be an innovative medicinal product, and products may not qualify for data exclusivity. Even if a product is considered to be an innovative medicinal product so that the innovator gains the prescribed period of data exclusivity, another company nevertheless could also market another version of the product if such company obtained marketing authorization based on an MAA with a complete independent and data package of pharmaceutical tests, preclinical tests and clinical trials.

Pediatric studies and exclusivity

Prior to obtaining a marketing authorization in the EU, applicants must demonstrate compliance with all measures included in an EMA-approved pediatric investigation plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP. The respective requirements for all marketing authorization procedures are laid down in Regulation (EC) No 1901/2006, the so-called Pediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The Pediatric Committee of the EMA, or PDCO, may grant deferrals for some medicines, allowing a company to delay development of the medicine for children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine for children is not needed or is not appropriate, such as for diseases that only affect the elderly population. Before an MAA can be filed, or an existing marketing authorization can be amended, the EMA determines that companies actually comply with the agreed studies and measures listed in each relevant PIP. If an applicant obtains a marketing authorization in all EU Member States, or a marketing authorization granted in the centralized procedure by the European Commission, and the study results for the pediatric population are included in the product information, even when negative, the medicine is then eligible for an additional six-month period of qualifying patent protection through extension of the term of the Supplementary Protection Certificate or SPC, provided an application for such extension is made at the same time as filing the SPC application for the product, or at any point up to two years before the SPC expires, even where the trial results are negative. 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 specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

Orphan drug designation and exclusivity

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the United States. In the EU 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 the necessary investment in its development; 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. 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 orphan market exclusivity period, no marketing authorization application shall be accepted, and no marketing authorization shall be granted 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. An orphan product can also obtain an additional two years of market exclusivity in the EU for pediatric studies conducted in compliance with a PIP. The ten-year market exclusivity 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 (i) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the authorized orphan product; (ii) the marketing authorization holder for the authorized orphan product consents to a second orphan medicinal product application; or (iii) the marketing authorization holder for the authorized orphan product cannot supply enough orphan medicinal product.

Regulatory requirements after a marketing authorization has been obtained

If an authorization for a medicinal product in the EU is obtained, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include:

- Compliance with the EU's stringent pharmacovigilance or safety reporting rules must be ensured. These rules can impose post-authorization studies and additional monitoring obligations.

- The manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the applicable EU laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC and Regulation (EC) No 726/2004. These requirements include compliance with EU cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the EU with the intention to import the active pharmaceutical ingredients into the EU.

- The marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the EU. Direct-to-consumer advertising of prescription medicines is prohibited across the EU.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the EU Member States, plus Norway, Liechtenstein and Iceland.

Brexit and the regulatory framework in the United Kingdom

On June 23, 2016, the electorate in the United Kingdom, or UK, voted in favor of leaving the EU, commonly referred to as Brexit, and the UK formally left the EU on January 31, 2020. There was a transition period during which EU pharmaceutical laws continued to apply to the UK, which expired on December 31, 2020. However, the EU and the UK have concluded a trade and cooperation agreement, or TCA, which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not provide for wholesale mutual recognition of UK and EU pharmaceutical regulations. At present, Great Britain has 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 currently continues to apply in Northern Ireland). Except in respect of the new EU Clinical Trials Regulation, the regulatory regime in Great Britain for medicines therefore largely aligns with EU regulations, however, it is possible that these regimes will diverge more significantly in the future now that Great Britain's regulatory system is independent from the EU and the TCA does not provide for mutual recognition of UK and EU pharmaceutical legislation.

On February 27, 2023, the UK government and the European Commission announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework." This new framework fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the UK. In particular, the Medicines and Healthcare products Regulatory Agency, or MHRA, the UK medicines regulator, will be responsible for approving all medicinal products destined for the UK market (i.e., Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. A single UK-wide MA will be granted by the MHRA for all medicinal products to be sold in the UK, enabling products to be sold in a single pack and under a single authorization throughout the UK. The Windsor Framework was approved by the European Union-United Kingdom Joint Committee on March 24, 2023, and the UK government and the EU will therefore enact legislative measures to bring it into law. On June 9, 2023, the MHRA announced that the medicines aspects of the Windsor Framework will apply starting on January 1, 2025.

Government regulation of the processing of personal data collected outside of the United States

If we continue to conduct ongoing or future clinical trials in the EEA and UK, we will continue to be subject to additional data protection restrictions. The collection and use of personal data in the EEA, is governed by the General Data Protection Regulation, or the GDPR, which became effective on May 25, 2018. The GDPR applies to the processing of personal data of data subjects in the EEA by any company established in the EEA and to companies established outside the EEA to the extent they process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. The GDPR sets forth data protection obligations for data controllers of personal data, including stringent requirements relating to notifying data subjects about how their personal data are being handled and how they can exercise their data protection rights, ensuring there is a valid legal basis to process personal data, and condition to process special categories of personal data (if this is consent, the requirements for obtaining consent carry a higher threshold), requirements to conduct data protection impact assessments for certain "high risk" processing, requirements to appoint a data protection officer where sensitive personal data are processed on a "large scale," limitations on retention of personal data, mandatory data breach notification in certain circumstances, requirements to ensure appropriate technical and organizational measures are in place to safeguard personal data, and "privacy by design" requirements, and also creates direct obligations on service providers acting as data processors.

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA, which may deviate slightly from the GDPR, may result in fines of up to 4% of a company's global revenues for the preceding financial year, or €20,000,000,

whichever is greater. Moreover, the GDPR grants data subjects the right to claim material and non-material damages resulting from infringement of the GDPR. Given the breadth and depth of changes in data protection obligations, maintaining compliance with the GDPR will require significant time, resources and expense, and we may be required to put in place additional controls and processes to ensure compliance with the new data protection rules. Further to the UK's exit from the EU on January 31, 2020, the GDPR ceased to apply in the UK but the UK incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law, referred to as the UK GDPR. The UK GDPR and the UK Data Protection Act 2018 set forth the UK's data protection regime, which is independent from but currently still aligned to the EU's GDPR. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the UK have significantly restricted the transfer of personal data to countries whose privacy laws it believes are inadequate, including the United States in certain circumstances, unless a derogation exists or adequate international transfer safeguards are put in place (for example, the European Commission approved Standard Contractual Clauses, and the UK International Data Transfer Agreement/Addendum) and transfer impact assessments carried out. Further, regulators and legislators in the U.S. are increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, Executive Order 14117, Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern, as implemented by Department of Justice regulations issued in December 2024, prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to countries of concern, including China. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. If we are unable to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere, the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business.

Human Capital Resources

As of December 31, 2025, we had 192 full-time employees. 34% of our employees have M.D. or Ph.D. degrees. Within our workforce, 80% of employees are engaged in research and development and 20% are engaged in business development, finance, legal, and general management and administration. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

We believe that our people are among our greatest assets and that a diverse and inclusive organization is more innovative and higher performing. We are committed to providing an inclusive, diverse and equitable environment for all employees, and creating an inclusive and collaborative culture that welcomes our differences and creates a safe space for employees to voice their different perspectives.

We are not only focused on recruiting top talent from a diverse range of backgrounds, industries and experiences, but also focused on retaining, developing and promoting our current employees. We maintain a robust onboarding program to ensure all new hires are grounded in our business and culture and we conduct periodic talent reviews to identify high performing and high potential talent within the organization. This data is used to inform specific development opportunities for current and future leaders, create leadership training opportunities, drive meaningful development conversations and enable succession planning for key roles. In addition to our broader talent strategy, we also foster an environment of continuous feedback through our quarterly check-in process where managers and employees share feedback and discuss development opportunities. We believe this combined approach to employee development drives a culture and environment where employees can thrive.

We regularly host company-wide sessions (virtual and onsite) where our leaders share updates on corporate initiatives and business strategy, and where our employees share scientific breakthroughs, celebrate development milestones, and recognize each other's contributions and accomplishments. Instead of an annual employee survey, we conduct several pulse checks per year to create a nimbler feedback-to-action loop, allowing us to respond to employee sentiment in a timelier fashion. These employee surveys help us measure employee engagement and inform future talent initiatives.

Corporate Information

We were incorporated under the laws of the State of Delaware on May 4, 2015 under the name Allostery, Inc. In December 2015, we changed our name to Relay Therapeutics, Inc. Our principal corporate office is located at 60 Hampshire Street, Cambridge, MA 02139, and our telephone number is (617) 370-8837. Our website address is www.relaytx.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.

Available Information

Our website address is www.relaytx.com. Our Annual Reports 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, or the Exchange Act, are available through the "Investors & Media" portion of our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Information on our website is not part of this Annual Report on Form 10-K or any of our other filings with the SEC unless specifically incorporated herein or therein by reference. In addition, our filings with the SEC may be accessed through the SEC's Interactive Data Electronic Applications system at www.sec.gov. All statements made in any of our filings with the SEC or documents available on our website, 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.

Our code of conduct, corporate governance guidelines and the charters of our Audit Committee, Research and Development Committee, Compensation Committee and Nominating and Corporate Governance Committee are available through the "Investors & Media" portion of our website.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. We believe the risks described below include risks that are material to us as well as other risks that may adversely affect our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also materially harm our business, financial condition, results of operations and growth prospects and could result in a complete loss of your investment. Consequently, you should not consider the following to be a complete discussion of all potential risks or uncertainties.

Risks Related to Our Product Candidates

Risks Related to Clinical Development

We have never successfully completed any large-scale, pivotal clinical trials, and we may be unable to do so for any product candidates we develop.

We have not yet demonstrated our ability to successfully complete any large-scale, pivotal clinical trials, obtain regulatory approvals, 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 commercialization. Our lead product candidate is in clinical development. We may not be able to file investigational new drug applications, or INDs, for any of our preclinical product candidates on the timelines we expect, if at all. For example, we may experience manufacturing delays or delays with IND-enabling studies. Moreover, we cannot be sure that once we have submitted an IND, the FDA will allow further clinical trials to begin, or that, once begun, issues will not arise that require us to suspend or terminate clinical trials. The FDA or other regulatory authorities may impose a clinical hold before or after a trial begins for a number of reasons outlined in FDA regulations, including if the FDA believes the study drug raises a significant risk of illness or injury. If the FDA imposes a clinical hold, trials may not commence or recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, the submission of an IND does not mean the FDA will allow clinical trials to begin and, if and when clinical trials do commence under an active IND, issues may arise that require suspension or termination of such trials. Further, commencing each of these clinical trials is subject to finalizing the trial design based on discussions with the FDA and other regulatory authorities. Any guidance we receive from the FDA or other regulatory authorities is subject to change. Regulatory authorities could change their position, including, on the acceptability of our trial designs or the clinical endpoints selected, which may require us to complete additional clinical trials or impose stricter approval conditions than we expect. Successful completion of our clinical trials is a prerequisite to submitting a new drug application, or NDA, to the FDA and a Marketing Authorization Application, or MAA, to the EMA for each product candidate and, consequently, the ultimate approval and commercial marketing of each product candidate. While we have active clinical trials for our lead product candidate, we do not know whether any of our current clinical trials will be completed on schedule, if at all, or whether any of our future clinical trials will begin on time or be completed on schedule, if at all.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;

- obtain approval for indications or patient populations that are not as broad as intended or desired;
- be subject to post-marketing requirements; or
- have the product removed from the market after obtaining marketing approval.

Clinical product development involves a lengthy and expensive process, with an uncertain outcome.

It is impossible to predict when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies and then conduct the required clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical development testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical and other nonclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. Our preclinical and other nonclinical studies and future clinical trials may not be successful.

From time to time, we may publish interim, top-line or preliminary data from our clinical trials. Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as more participants enroll and as data mature. Preliminary or top-line data also remain subject to cleaning and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

We may experience delays in completing our preclinical studies and initiating or completing clinical trials, and we may experience numerous unforeseen events during, or as a result of, any future clinical trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- existing clinical trial sites may drop out of the clinical trial, which may require that we add new clinical trial sites or investigators;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional nonclinical studies or clinical trials or we may decide to abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol;
- we may elect to, or regulators or IRBs or ethics committees may require us or our investigators to, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- we may not be able to adequately project the timing and quantity of our product candidates or any other materials necessary to conduct clinical trials of our product candidates;

- the supply or quality of our product candidates, other therapies used in our clinical trials or any other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate or not available in a reasonable timeframe, and any transfer of manufacturing activities may require unforeseen manufacturing or formulation changes; and

- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs or ethics committees to suspend or terminate the clinical trials, or reports may arise from nonclinical studies or clinical testing of other therapies that raise safety or efficacy concerns about our product candidates.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions at which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose a suspension or termination or clinical hold due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA may disagree with our clinical trial design or our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials.

Our product development costs will also increase if we experience delays in preclinical studies, clinical trials or regulatory approvals. We do not know whether any of our future clinical trials will begin as planned, or whether any of our current or future clinical trials will need to be restructured or will be completed on schedule, if at all. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. Any delays in our preclinical or current or future clinical development programs may harm our business, financial condition and prospects significantly.

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

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In particular, because we will be deploying our drug discovery platform across a broad target space, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

In addition to the competitive clinical trial environment, the eligibility criteria of our planned clinical trials will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure to assure their cancer or other disease is either severe enough or not too advanced to include them in a study. Additionally, the process of finding patients may prove costly. Where our clinical trials involve multiple combination arms, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. We also may not be able to identify, recruit and enroll a sufficient number of patients to complete our clinical studies because of the perceived risks and benefits of the product candidates under study or any of the other therapies used in combination with such product candidates, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical trial sites for prospective patients, and the patient referral practices of physicians. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed.

We have engaged and may continue to engage third parties to develop companion diagnostics for use in our clinical trials, but such third parties may not be successful in developing such companion diagnostics, furthering the difficulty in identifying patients with the targeted genetic mutations for our clinical trials. Further, if we are required to develop companion diagnostics and are unable to include patients with the targeted genetic mutations, this could compromise our ability to seek participation in the FDA's expedited review and development programs, including Breakthrough Therapy Designation and Fast Track Designation, or otherwise to seek to accelerate clinical development and regulatory timelines. The FDA has indicated that if we continue RLY-2608 in a specific biomarker-defined population, a companion diagnostic device will be required to ensure its safe and effective use. If any of our future third-party companion diagnostic partners is unable or unwilling to obtain or maintain regulatory approval for a companion diagnostic for any of our product candidates, regulatory approval for such product candidates, if obtained at all, may be delayed.

Clinical trial enrollment may be affected by other factors including:

- the severity or rarity of the disease under investigation;

- the eligibility criteria for the clinical trial in question;

- the availability of an appropriate genomic screening test;
- the perceived risks and benefits of the product candidate under study;
- the resources and efforts required to facilitate timely enrollment in clinical trials;
- the availability of approved products that treat the same indications as our product candidates;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective patients; and
- factors we may not be able to control that may limit patients, principal investigators or staff or clinical site availability, such as uncertain geopolitical conditions or current or future pandemics.

Additionally, for certain of our current and future clinical trials, we have and may utilize, an "open-label" trial design. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an active drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results with any of our product candidates when studied in a blinded trial.

Positive data from preclinical or early clinical studies of our product candidates are not necessarily predictive of the results of later clinical studies and any future clinical trials of our product candidates. If we cannot replicate the positive data from our preclinical or early clinical studies of our product candidates in our future clinical trials, we will be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates.

Any positive data from our preclinical or early clinical studies of our product candidates may not necessarily be predictive of the results of later clinical studies and any future clinical trials of our product candidates. Similarly, even if we are able to complete our planned preclinical and clinical studies or any future clinical trials of our product candidates according to our current development timeline, the positive data from such preclinical or early clinical studies and clinical trials of our product candidates may not be replicated in subsequent nonclinical studies or clinical trial results.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical and other nonclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical, other nonclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA, EMA or other regulatory authority approval.

Our current or future clinical trials or those of future collaborators or licensees may reveal significant adverse events not seen in our preclinical or other nonclinical studies or early clinical data and may result in a safety profile that would inhibit regulatory approval or market acceptance of any of our product candidates.

Before obtaining regulatory approvals for the commercial sale of any products, we must demonstrate through lengthy, complex and expensive preclinical or other nonclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical or other nonclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials also may fail to show the desired safety and efficacy profile despite having progressed through preclinical or other nonclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our product candidates.

We are developing certain product candidates and may develop future product candidates, in combination with one or more cancer or other therapies. The uncertainty resulting from the use of our product candidates in combination with other therapies may make it difficult to accurately predict side effects in future clinical trials.

As is the case with many treatments for cancer and rare diseases, it is likely that there may be side effects associated with the use of our product candidates. If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our clinical trials, or we may be required to abandon the clinical trials or our development efforts of one or more product candidates altogether. We, the FDA or other applicable regulatory authorities, or an IRB may suspend or terminate clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. If used in combination with other therapies in the future, our product candidates could exacerbate adverse events associated with those therapies, as well as result in adverse events from drug-drug interaction. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage clinical trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product 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 developments could materially harm our business, financial condition and prospects.

Although we intend to explore other therapeutic opportunities, in addition to the product candidates that we are currently developing, we may fail to identify viable new product candidates for clinical development for a number of reasons. If we fail to identify additional potential product candidates, our business could be materially harmed.

Research programs to pursue the development of our existing and planned product candidates for additional indications and to identify new product candidates and disease targets require substantial technical, financial and human resources whether or not they are ultimately successful. For example, as part of our research efforts, we develop various protein models and make predictions as to how molecules might move, with subsequent validation efforts in our and our CROs' labs. There can be no assurance that we will find potential additional targets using this approach, that any such targets will be tractable, that preclinical development of any of our research programs will be successful or that any clinical validations will be successful. Our research programs may initially show promise in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including:

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

Our early-stage discovery programs and preclinical development programs may not reach clinical development on the timelines we expect or ever. Because we have limited financial and human resources, we intend to initially focus on research programs and product candidates for a limited set of indications. As a result, we may forgo or delay pursuit of opportunities with other product candidates or for other indications that later prove to 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 or in collaboration with third parties, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

We intend to develop our lead product candidate, may develop other current product candidates and potentially future product candidates, in combination with other therapies, which exposes us to additional risks.

We intend to develop zovegalisib and may develop our other current product candidates and future product candidates, for use in combination with one or more currently approved cancer or other therapies. Even if any product candidate we develop was to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to bear the risks that the FDA or similar regulatory authorities could revoke approval of the therapy used in combination with our product candidates or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer. This could result in our own products being removed from the market or being less successful commercially.

We are also evaluating zovegalisib and may in the future evaluate other current product candidates or any future product candidates in combination with one or more cancer or other therapies that have not yet been approved for marketing by the FDA or similar regulatory

authorities. For example, in June 2024, we entered into a clinical trial collaboration with Pfizer to evaluate atirmociclib, Pfizer's investigative selective-CDK4 inhibitor, in combination with zovegalisib and fulvestrant in patients with PI3Kα-mutated, HR+, HER2- metastatic breast cancer and are evaluating this combination in our ReDiscover Trial. We will not be able to market and sell any of our product candidates we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval. In addition, unapproved therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, supply and/or manufacturing issues, delay in their clinical trials, and lack of FDA approval.

The uncertainty resulting from the use of our product candidates in combination with other approved or unapproved therapies may make it difficult to accurately predict side effects in current or future clinical trials. If the FDA or similar regulatory authorities do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with our lead product candidate or any other current or future product candidate we develop, we may be unable to obtain approval of or market any of such product candidates.

Our product candidates utilize a novel mechanism of action and novel binding locations, which may result in greater research and development expenses, regulatory issues that could delay or prevent approval, or discovery of unknown or unanticipated adverse effects.

Our product candidates utilize novel mechanisms of action and novel binding locations, which may result in greater research and development expenses, regulatory issues that could delay or prevent approval, or discovery of unknown or unanticipated adverse effects. Our Dynamo® platform uses advanced computational models in tight integration with our medicinal chemistry, structural biology, enzymology and biophysics capabilities to predict and design the compounds that will achieve the most desirable characteristics, including potency, selectivity, bioavailability, and drug-like properties. A disruption in any of these capabilities may have significant adverse effects in our abilities to expand our Dynamo® platform, and we cannot predict whether we will continue to have access to these capabilities in the future to support our Dynamo® platform. In addition, there can be no assurance that we will be able to rapidly identify, design and synthesize the necessary compounds or that these or other problems related to the development of this novel mechanism will not arise in the future, which may cause significant delays, or raise problems that we may not be able to resolve.

Regulatory approval of novel product candidates such as ours can be more expensive, riskier and take longer than for other, more well-known or extensively studied pharmaceutical or biopharmaceutical product candidates due to our and regulatory agencies' lack of experience with them. The novelty of our mechanism of action may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. The novel mechanism of action also means that fewer people are trained in or experienced with product candidates of this type, which may make it more difficult to find, hire and retain personnel for research, development and manufacturing positions. Because our inhibitors utilize a novel mechanism of action that has not been the subject of extensive study compared to more well-known product candidates, there is also an increased risk that we may discover previously unknown or unanticipated adverse effects during our preclinical or other nonclinical studies and clinical trials. Any such events could adversely impact our business prospects, financial condition and results of operations.

We are conducting, or have filed clinical trial applications to conduct, clinical trials for our product candidates outside the United States, and the FDA and similar foreign regulatory authorities may not accept data from such trials.

We have conducted or are conducting, or have filed clinical trial applications to conduct, additional clinical trials outside the United States, including Australia, the United Kingdom, Europe, South America and Asia and may conduct, or file clinical trial applications to conduct, additional clinical trials in other foreign jurisdictions in the future. The acceptance of trial data from clinical trials conducted outside the United States by the FDA may be subject to certain conditions. In cases where data from clinical trials conducted outside the United States are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice; (ii) the trials were performed by clinical investigators of recognized competence and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any similar foreign regulatory authority will accept data from clinical trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any similar foreign regulatory authority does not accept such data, it would result in the need for additional clinical trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

Risks Related to Obtaining Regulatory Approvals

If we are not able to obtain, or if delays occur in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by similar authorities in other countries. Before we can commercialize any of our product candidates, we must obtain marketing approval. Currently, all of our product candidates are in development, and we have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. It is possible that our product candidates, including any product candidates we may seek to develop in the future, will never obtain regulatory approval. We have only limited experience in filing and supporting the applications necessary to gain regulatory approvals and expect to rely on third-party CROs and/or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive nonclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. In addition, regulatory authorities may find fault with our manufacturing process or facilities or that of third-party contract manufacturers. We may also face greater than expected difficulty in manufacturing our product candidates.

The process of obtaining regulatory approvals, both in the United States and abroad, is expensive and often takes many years. If the FDA or a similar foreign regulatory authority requires that we perform additional nonclinical studies or clinical trials, approval, if obtained at all, may be delayed. The length of such a delay varies substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted NDA, 510(k) or other premarket approval application, or PMA, or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and similar authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional nonclinical, clinical or other studies. It is also unclear how FDA marketing approval policies along with FDA interpretations of law or regulatory discretion could change as a result of the U.S. Supreme Court's decision to overturn prior established case law giving deference to agency decisions and interpretations. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or similar foreign regulatory authorities may disagree with or change their position regarding the design or implementation of our clinical trials;
- we may not be able to enroll a sufficient number of patients in our clinical studies;
- we may be unable to demonstrate to the satisfaction of the FDA or similar foreign regulatory authorities that a product candidate is safe and effective for its proposed indication or a related companion diagnostic is suitable to identify appropriate patient populations;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or similar foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or similar foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or similar foreign regulatory authorities may find deficiencies with or fail to approve 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 or similar foreign regulatory authorities may significantly change such that our clinical data are insufficient for approval.

Even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, thereby narrowing the commercial potential of the product candidate. In addition, regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does

not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

Risks Related to Commercialization

The incidence and prevalence for target patient populations of our product candidates have not been established with precision. If the market opportunities for our product candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability will be adversely affected, possibly materially.

Our projections of both the number of people who have the diseases our product candidates are targeting, as well as the subset of people with such disease who have the potential to benefit from treatment with any of our product candidates, are based on estimates.

The total addressable market opportunity will ultimately depend upon, among other things, the diagnosis criteria included in the final label, and, if our product candidates are approved for sale for these indications, acceptance by the medical community and patient access, product pricing and reimbursement. The number of patients with cancers and solid tumors or other applicable diseases may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. 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. For example, in December 2024, we entered into the exclusive global licensing agreement with Elevar for lirafugratinib, and in early 2025, we reduced our research-stage programs, allowing us to focus our resources on the remainder of our portfolio. These and other prioritization decisions may prove to be the wrong choice and may adversely affect our business.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new products in the biopharmaceutical and related industries is highly competitive. We compete in the segments of the pharmaceutical, biotechnology, and other related markets that address computationally focused structure-based drug design in cancer and genetic diseases. There are other companies focusing on structure-based drug design to develop therapies in the fields of cancer and other diseases. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. These companies include divisions of large pharmaceutical companies and biotechnology companies of various sizes. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Any product candidates that we successfully develop and commercialize will compete with currently approved therapies and new therapies that may become available in the future from segments of the pharmaceutical, biotechnology and other related markets that pursue precision medicines. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products. We believe principal competitive factors to our business include, among other things, the accuracy of our computations and predictions, ability to integrate computational and experimental capabilities, ability to successfully transition research programs into clinical development, ability to raise capital, and the scalability of the platform, pipeline, and business.

Many of the companies that we compete against or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products 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. Smaller or earlier stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific, clinical and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, we cannot predict whether our current competitive advantages will remain in place in the future. If these or other barriers to entry do not remain in place, other companies may be able to more directly or effectively compete with us.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we or our collaborators may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

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

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments. Sales of these or other product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. See "*Business – Governmental Regulation – Insurance coverage and reimbursement.*"

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

Factors payors consider in determining reimbursement are based on whether the product is (i) a covered benefit under its health plan; (ii) safe, effective and medically necessary; (iii) appropriate for the specific patient; (iv) cost-effective; and (v) neither experimental nor investigational.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price, or ASP, and best price. Penalties may apply in some cases when such metrics are not submitted accurately and in a timely manner. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

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. For example, the EU provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the EU do not follow price structures of the U.S. and generally prices tend to be significantly lower.

Risks Related to Our Reliance on Third Parties

We have relied on, and expect to continue to rely on, third parties to conduct our current and future clinical trials of our product candidates, as well as investigator-sponsored clinical trials of our product candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We do not have the ability to independently conduct clinical trials. We rely and expect to continue to rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct or otherwise support clinical trials for our product candidates. We may also rely on academic and private non-academic institutions to conduct and sponsor clinical trials relating to our product candidates. We will not control the design or conduct of the investigator-sponsored trials, and it is possible that the FDA or non-U.S. regulatory authorities will not view these investigator-sponsored trials as providing adequate support for future clinical trials, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results.

Such arrangements will likely provide us certain information rights with respect to the investigator-sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory filings, resulting from the investigator-sponsored trials. However, we would not have control over the timing and reporting of the data from investigator-sponsored trials, nor would we own the data from the investigator-sponsored trials. If we are unable to confirm or replicate the results from the investigator-sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development of our product candidates. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data prove to be inadequate compared to the first-hand knowledge we might have gained had the investigator-sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected.

We rely and expect to continue to rely heavily on these parties for execution of clinical trials for our product candidates and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We, our principal investigators and our CROs are required to comply with regulations, including Good Clinical Practices, or GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and similar foreign regulatory authorities for any products in clinical development, including the EMA and the MHRA. These regulatory authorities enforce GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we, our principal investigators or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or similar foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, these regulatory authorities will determine that any of our future clinical trials will comply with GCPs. In addition, our clinical trials must be conducted with product candidates produced under current Good Manufacturing Practice, or cGMP, regulations. Our failure or the failure of our principal investigators or CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we designed our first-in-human clinical trials of our lead product candidate and intend to design the future clinical trials for any other product candidates that we develop, we expect that CROs will conduct all of our clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, are outside of our direct control. Our reliance on third parties to conduct future clinical trials also results in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If the principal investigators or CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of our product candidates may be delayed, we may not be able to obtain regulatory approval and commercialize our product candidates, or our development program may be materially and irreversibly harmed. If we are unable to rely on clinical data collected by our principal investigators or CROs, we could be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party principal investigators or CROs terminate, we may not be able to enter into arrangements with alternative CROs. If principal investigators or CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such principal investigators or CROs are associated with may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, we believe that our financial results and the commercial prospects for our

product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

We contract with third parties for the manufacture of our product candidates for preclinical development, clinical testing, and expect to continue to do so for commercialization. We also rely, and expect to continue to rely, on third parties for the supply of any investigational products, standard-of-care drugs and comparator agents used in our clinical trials. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or other therapies or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We do not currently own or operate, nor do we have any plans to establish in the future, any manufacturing facilities or personnel. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical development and clinical testing, as well as for the commercial manufacture of our products if any of our product candidates receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

The facilities used by our contract manufacturers to manufacture our product candidates must be inspected by the FDA pursuant to pre-approval inspections that will be conducted after we submit our marketing applications to the FDA. We do not control the manufacturing process of, and will be completely dependent on, our contract manufacturers for compliance with cGMPs in connection with the manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to pass regulatory inspections and/or maintain regulatory compliance for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a similar foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it finds deficiencies or withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Further, our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, if approved, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our product candidates.

We may be unable to establish any 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:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Our product candidates and any products that we may develop may compete with other product candidates and approved products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Due to capacity constraints at cGMP manufacturers, we have been required to forecast the amount of clinical trial supply needed for our clinical trials further in advance than had typically been required, and there is limited flexibility to adjust our manufacturing needs as our clinical trials progress, which may lead to added costs or delays in our clinical trials.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We are also unable to predict how the effects of ongoing geopolitical conflicts may affect our third-party manufacturers, including any potential disruptions to our global supply chain. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers, which we may not be able to do on reasonable terms, if at all, or manufacture the materials ourselves, for which we may not have the capabilities or resources. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original contract manufacturing organization, or CMO, and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. Changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. We may incur added costs and delays in identifying and qualifying any such replacement. Furthermore, a CMO may possess technology related to the manufacture of our product candidates that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates.

We currently rely on foreign CMOs for the manufacture of certain of our product candidates for preclinical development and clinical testing and will likely continue to do so in the future. Foreign CMOs may be subject to U.S. legislation or investigations, such as the previously proposed BIOSECURE Act in the United States, sanctions, trade restrictions and other foreign regulatory requirements, which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material, delay or impact clinical trials, have an adverse effect on our ability to secure significant commitments from governments to purchase our product candidates, if ever approved, and could adversely affect our financial condition and business prospects.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We also rely, and expect to continue to rely, on third parties for the supply of any investigational products, standard-of-care drugs or comparator agents used in our clinical trials. Any supply chain challenges may affect our ability to supply clinical sites with any investigational products, standard-of-care drugs and/or comparator agents that we use in our clinical trials and may prevent us from enrolling subjects into our clinical trials, may result in increased costs for our clinical trials, and may otherwise delay, prevent or impair our development efforts.

The third parties upon whom we rely for the supply of the active pharmaceutical ingredients, drug product and starting materials used in our product candidates are our sole source of supply, and the loss of any of these suppliers could significantly harm our business.

The active pharmaceutical ingredients, or API, drug product and starting materials used in our product candidates are supplied to us primarily from single-source suppliers. Our ability to successfully develop our product candidates, and to ultimately supply our commercial products in quantities sufficient to meet the market demand, depends in part on our ability to obtain the API, drug product and starting materials for these products in accordance with regulatory requirements and in sufficient quantities for clinical testing and commercialization. We do not currently have arrangements in place for a redundant or second-source supply of any such API, drug product or starting materials in the event any of our current suppliers of such API, drug product or starting materials ceases its operations for any reason. If any of our third-party suppliers or manufacturers ceases its operations for any reason or is unable or unwilling to supply API, drug product or starting material in sufficient quantities, on the timelines necessary, or at acceptable prices, to meet our needs, it could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects. We are also unable to predict how changing global economic conditions or ongoing geopolitical conflicts and related global economic sanctions, or potential global health concerns will affect our third-party suppliers and manufacturers. Any negative impact of such matters on our third-party suppliers and manufacturers may also have an adverse impact on our results of operations or financial condition.

For all of our product candidates, we intend to identify and qualify additional manufacturers to provide such API, drug product and starting materials prior to or after submission of an NDA to the FDA and/or an MAA to the EMA. We are not certain, however, that our single-source suppliers will be able to meet our demand for their products, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers.

Establishing additional or replacement suppliers for the API, drug product and starting materials used in our product candidates, if required, may not be accomplished quickly. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory inspection or approval, which could result in further delay. While we seek to maintain adequate inventory of the API, drug product and starting materials used in our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain such API, drug product or starting materials from alternate sources at acceptable prices in a timely manner could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

We have and may enter into other licenses or collaborations with third parties for the research, development, manufacture and commercialization of one or more of our programs or product candidates. If these licenses or collaborations are not successful, our business could be adversely affected.

We have entered into and may enter into licenses or collaborations with third parties for one or more of our programs or product candidates, such as the Elevar Agreement to develop and commercialize lirafugratinib. If we enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that any licensees or collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our licensees' or collaborators' abilities to successfully perform the functions assigned to them.

Any licenses or collaborations we have entered into or will enter into may pose risks, including the following:

- Licensees or collaborators may have significant discretion in determining the efforts and resources that they will apply to these licenses or collaborations;

- Licensees or collaborators may not perform their obligations as expected;
- The clinical trials conducted as part of these licenses or collaborations may not be successful;
- Licensees or collaborators may not pursue development and/or commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the licensees' or collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- Licensees or collaborators may delay clinical trials, provide insufficient funding for clinical trials, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- We may not have access to, or may be restricted from disclosing, certain information regarding product candidates being developed or commercialized under a license or collaboration and, consequently, may have limited ability to inform our stockholders about the status of such product candidates;
- Licensees or collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the licensees or collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- Product candidates developed in collaboration with us may be viewed by any licensee or collaborator as competitive with their own product candidates or products, which may cause licensees or collaborators to cease to devote resources to the commercialization of our product candidates;
- A licensee or collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product candidate;
- Disagreements with licensees or collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any programs or product candidates, may cause delays or termination of the research, development, manufacture or commercialization of such programs or product candidates, may lead to additional responsibilities for us with respect to such programs or product candidates or may result in litigation or arbitration, any of which would be time-consuming and expensive;
- Licensees or collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- Disputes may arise with respect to the ownership of intellectual property developed pursuant to our licenses or collaborations;
- Licensees or collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- Licenses or collaborations may be terminated for the convenience of the licensee or collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates. For example, Genentech terminated the Genentech Agreement for convenience effective as of January 7, 2025.

If our licenses or collaborations do not result in the successful development and commercialization of products, or if one of any future licensees or collaborators terminates its agreement with us, we may not receive any milestone or royalty payments under the license or collaboration. If we do not receive the payments we expect under these agreements, our development of product candidates could be delayed and we may need additional resources to develop our product candidates. All of the risks relating to product development, regulatory approval and commercialization summarized and described in this report also apply to the activities of our licensees or collaborators.

In addition, if any licensee or collaborator terminates its agreement with us, we may find it more difficult to attract new licensees or collaborators and our reputation among the business and financial communities could be adversely affected.

We may seek to establish additional licenses and/or collaborations, and, if we are not able to establish them on commercially reasonable terms, or at all, we may have to alter our development and commercialization plans.

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to license to, or collaborate with, additional pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate licensees and/or collaborators. Whether we reach a definitive agreement for a license or collaboration will depend, among other things, upon our assessment of the licensee's or collaborator's resources and expertise, the terms and conditions of the proposed license or collaboration and the proposed licensee's or collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The licensee or collaborator may also consider alternative product candidates or technologies for similar indications that may be available to license or collaborate on and whether such a license or collaboration could be more attractive than the one with us for our product candidate. The terms of any additional licenses or collaborations or other arrangements that we may establish may not be favorable to us.

We may also be restricted under license or collaboration agreements from entering into future agreements on certain terms with potential licensees or collaborators. Licenses and collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future licensees and/or collaborators.

We may not be able to negotiate additional licenses or collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to license or collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

We may be required to pay certain milestones, royalties or other payments under our license or collaboration agreements with third-party licensors or collaborators, which may adversely affect the overall profitability of any products that we may seek to commercialize or adversely impact the value of other transactional opportunities.

Under our current and future license or collaboration agreements, including our DESRES Agreement, we may be required to pay milestones, royalties and other payments based on our revenues, including revenues from product sales, and these milestones and royalty payments could adversely affect the overall profitability of any products that we may seek to commercialize. Moreover, we may be subject to certain payment obligations under our current and future license agreements, including our DESRES Agreement, in connection with certain transactions. These payment obligations may decrease the value to us of certain transactional opportunities or otherwise burden our ability to enter into such transactions.

In order to maintain our rights under our current or future license agreements, we may need to meet certain specified milestones in the development of our product candidates. Further, our licensors (or their licensors), licensees or other strategic collaborators may dispute the terms, including amounts, that we are required to pay under the respective license or collaboration agreements. If these claims result in a material increase in the amounts that we are required to pay to our licensors or collaborators, or in the event of a claim of breach of the license, our ability to research, develop and obtain approval of product candidates or to commercialize our products could be significantly impaired.

Risks Related to Our Financial Position and Ability to Raise Additional Capital

Risks Related to Our Operating History

We are a biopharmaceutical company with a limited operating history.

We are a biopharmaceutical company with a limited operating history and have incurred net losses in each year since our inception. Our net losses were $276.5 million, $337.7 million, and $342.0 million for the years ended December 31, 2025, 2024, and 2023, respectively. We had an accumulated deficit of $2.0 billion as of December 31, 2025. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We commenced operations in May 2015. Since inception, we have focused substantially all of our efforts and financial resources on developing our Dynamo® drug discovery platform and product candidates. We have no products approved for commercial sale and therefore have never generated any revenue from product sales, and we do not expect to in the foreseeable future. We have not obtained regulatory approvals for any of our product candidates and there is no assurance that we will obtain approvals in the future. We expect to continue to incur significant expenses and operating losses over the next several years and for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' deficit and working capital.

We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.

Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant research and development expenses in connection with the commencement and continuation of clinical trials of our product candidates. In addition, if we obtain marketing approval for our product candidates, we will incur significant sales, marketing, and outsourced-manufacturing expenses. We will also continue to incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant operating losses for the foreseeable future. In the past, we have implemented internal restructurings and reorganizations designed to reduce the size and costs of our operations, improve operational efficiencies, enhance our ability to pursue market opportunities, and accelerate our development initiatives. If there are unforeseen expenses associated with such realignments in our business strategies, and we incur unanticipated charges or liabilities, we may not be able to effectively realize the expected cost savings or other benefits of such actions, which could have adverse effects on our business, operating results, and financial condition. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

The amount of our future losses is uncertain and our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline. Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- our ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts;
- our ability to obtain marketing approval for our product candidates, and the timing and scope of any such approvals we may receive;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;
- the level of demand for our product candidates should they receive approval, which may vary significantly;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapeutics that compete with our product candidates;
- our ability to effectively realize the expected cost savings and other benefits of internal restructurings;
- the changing and volatile U.S. and global economic environments or ongoing geopolitical conflicts; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or securities analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

We have no products approved for commercial sale and we have not generated any revenue from product sales.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have no products approved for commercial sale, we have not generated any revenue from our product sales and we do not expect to generate any revenue from the sale of products in the

near future. We do not expect to generate significant revenue unless and until we obtain marketing approval of, and begin to sell one or more of our product candidates. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- successfully complete preclinical studies;
- successfully enroll subjects in, and complete, clinical trials;
- have our IND applications go into effect for our planned clinical trials or future clinical trials;
- receive regulatory approvals from applicable regulatory authorities;
- initiate and successfully complete all safety studies required to obtain U.S. and foreign marketing approval for our product candidates;
- establish commercial manufacturing capabilities or make arrangements with third-party manufacturers for clinical supply and commercial manufacturing;
- obtain and maintain patent and trade secret protection or regulatory exclusivity for our product candidates;
- launch commercial sales of our product candidates, if and when approved, whether alone or in partnership or collaboration with others;
- obtain and maintain acceptance of the product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively compete with other therapies;
- obtain and maintain healthcare coverage and adequate reimbursement;
- enforce and defend intellectual property rights and claims;
- take precautionary measures to help minimize the risk of any future pandemics or outbreaks similar to COVID-19 to our employees; and
- maintain a continued 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 may experience significant delays in our commercialization efforts or we may be unable to successfully commercialize our product candidates at all, which would materially harm our business and prospects. In addition, if we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

Risks Related to Raising Additional Capital

We will need to raise substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate some of our product development programs or commercialization efforts.

The development of pharmaceutical products is capital-intensive. We have programs in clinical and preclinical development. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, initiate clinical trials of, and seek marketing approval for, our product candidates. In addition, depending on the status of regulatory approval or, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. We may also need to raise additional funds sooner if we choose to pursue additional indications and/or geographies for our product candidates or otherwise expand more rapidly than we presently anticipate. Furthermore, we continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or fail to do so on attractive terms, we would be forced to delay, reduce or eliminate certain of our research and development programs or future commercialization efforts.

We expect that our existing cash and cash equivalents and investments will be sufficient to fund our operations through at least the next 12 months. Our future capital requirements will depend on and could increase significantly as a result of many factors, including:

- the impact of any business interruptions to our operations, including the timing and enrollment of patients in our planned clinical trials, or to those of our manufacturers, suppliers, or other vendors, resulting from any public health crisis or ongoing geopolitical conflicts and related global economic sanctions;

- the scope, progress, results and costs of our current and future clinical trials of our lead product candidate and additional preclinical research of our other programs;

- the scope, progress, results and costs of drug discovery, preclinical research and clinical trials for our other product candidates;

- the number of future product candidates that we pursue and their development requirements;

- the costs, timing and outcome of regulatory review of our product candidates;

- our ability to establish and maintain licenses or collaborations on favorable terms, if at all;

- the success of any existing or future licenses or collaborations that we may enter into with third parties;

- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates;

- the achievement of milestones or occurrence of other developments that trigger payments under any existing or future license or collaboration agreements, if any;

- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under any existing or future license or collaboration agreements, if any;

- the costs and timing of future commercialization activities, including drug sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval, to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of any licensee or collaborator that we may have at such time;

- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;

- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;

- our headcount growth and associated costs if and/or as we expand our business operations and our research and development activities; and

- the costs of operating as a public company.

Identifying potential product candidates and conducting preclinical development testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Disruptions in the financial markets may make equity and debt financing more difficult to obtain, and may have a material adverse effect on our ability to meet our fundraising needs. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or otherwise at an earlier stage than otherwise would be desirable and

we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidate or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

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 can generate substantial product revenues, we expect to finance our cash needs through a combination of private and public equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, the ownership interest of our stockholders will be diluted, and the terms of those securities may include liquidation or other preferences that materially adversely affect their rights as a common stockholder. We may offer and sell up to an aggregate amount of $250.0 million of our common stock from time to time in "at the market" offerings pursuant to the sales agreement, or the 2024 Sales Agreement, with TD Securities (USA) LLC, or TD Securities, subject to the limitations thereof. As of December 31, 2025, we have not sold any shares of common stock under the 2024 Sales Agreement. Debt financing, if available, would increase our fixed payment obligations and 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 funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Risks Related to Public Health Matters and the Global Economy

Any future pandemic, epidemic, or outbreak of an infectious disease similar to the COVID-19 pandemic could affect our business and our financial results and could cause disruption to the development of our product candidates.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. A public health crisis similar to the COVID-19 pandemic could adversely impact our preclinical, other nonclinical or clinical trial operations, and we may experience delays in initiating, or fail to initiate, IND-enabling studies, recruiting and retaining patients, principal investigators and site staff for our clinical trials, dosing of patients in our clinical trials as well as in activating new trial sites, and protocol deviations. The negative impact of any such public health crisis on patient enrollment or treatment or the execution of our product candidates could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and have a material adverse effect on our financial results.

Any unforeseen disruptions arising from a public health crisis, including potential shutdowns or disruptions of businesses and government agencies, such as the SEC or FDA, could have a material adverse effect on our business and our results of operation and financial condition. Further, uncertainty around these and related issues could lead to adverse effects on the economy of the United States and other economies, which could impact our ability to raise the necessary capital needed to develop and commercialize our product candidates.

Global economic and political conditions, including economic uncertainty tied to interest rates, credit and financial market instability, and uncertainty related to ongoing geopolitical conflicts, are difficult to mitigate and could pose challenges to our growth and profitability and could adversely affect our business, financial condition or results of operations.

Unstable market and economic conditions may have adverse consequences on our business, financial condition or results of operations. In recent years, the global economy, in particular the credit and financial markets, has experienced significant volatility and disruptions, including diminished liquidity and credit availability, volatility in commodity prices, declines in consumer confidence and economic growth, and supply chain interruptions. Other factors, including rising interest rates and record inflation, may also increase the general cost of doing business. In 2023, the closures of Silicon Valley Bank and Signature Bank and their placement into receivership with the Federal Deposit Insurance Corporation, or FDIC, created bank-specific and broader financial institution liquidity risk and concerns. Although the Department of the Treasury, the Federal Reserve, and the FDIC jointly released a statement that depositors at Silicon Valley Bank and Signature Bank would have access to their funds, even those in excess of the standard FDIC insurance limits, under a systemic risk exception, future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages, impair the ability of companies to access near-term working capital needs, and create additional market and economic uncertainty. There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur.

Continued economic uncertainty caused by these and other factors, including political instability, conflicts or crises, at the global level or involving individual countries or regions and any associated economic sanctions, could result in a variety of risks to our business, including difficulty in enrolling participants in our clinical trials, difficulty in forecasting our financial results and managing inventory levels, increases in our business costs, which in turn affect our ability to develop our current and future product candidates, and negatively impacting our ability to raise additional capital when needed on acceptable terms, if at all. In addition, political developments impacting government spending and international trade, including changes in trade agreements, potential government shutdowns and trade disputes and tariffs, including tariffs that have been or may in the future be imposed by the United States or other countries and future legislation or actions taken by the United States or other countries that restrict trade, and protectionist or retaliatory measures taken by the United States or other countries, may negatively impact markets and cause weaker macroeconomic conditions. These global economic and political factors have also strained and could continue to strain certain of our suppliers and manufacturers, possibly resulting in supply disruptions or increased raw material or manufacturing costs, or adversely impacting their ability to manufacture clinical trial materials for our product candidates. Any of the foregoing could harm our business and prospects and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our operations.

Significant political, trade, regulatory developments, and other circumstances beyond our control, could have a material adverse effect on our financial condition or results of operations.

Significant political, trade, or regulatory developments, such as those stemming from the change in U.S. federal administration, are difficult to predict and may have a material adverse effect on us. Similarly, changes in U.S. federal policy that affect the geopolitical landscape could give rise to circumstances outside our control that could have negative impacts on our business operations. In 2017, the U.S. Congress and the Trump administration made substantial changes to U.S. policies, which included comprehensive corporate and individual tax reform. In addition, the Trump administration called for significant changes to U.S. trade, healthcare, immigration and government regulatory policy. Since the start of the Trump administration in 2025, U.S. policy changes have been implemented at a rapid pace and additional changes are likely. Changes to U.S. policy implemented by the U.S. Congress, the Trump administration or any new administration have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. The United States has imposed blanket 10% tariffs on virtually all imports to the U.S. and significantly higher so-called reciprocal tariffs applicable to imports from many countries. On April 9, 2025, the U.S. announced a temporary pause on its reciprocal tariffs applicable to many countries, while increasing the tariffs applicable to imports from China. The Trump administration has threatened to continue to broadly impose tariffs and increase existing tariffs, which could lead to corresponding punitive actions by the countries with which the U.S. trades. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented or threatened to implement retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or results of operations. Until we know what policy changes are made, whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them.

Risks Related to Our Intellectual Property

Risks Related to Protecting Our Intellectual Property

If we are unable to adequately protect our proprietary technology or obtain and maintain patent protection for our technology and products 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 commercialize our technology and products will be impaired.

Our commercial success will depend in part on our ability to obtain and maintain proprietary or intellectual property protection in the United States and other countries for our product candidates, and our core technologies, including our novel target discovery technology and our proprietary compound library and other know-how. We seek to protect our proprietary and intellectual property position by, among other methods, filing patent applications in the United States and abroad related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position. Other than our Eurasian, Japanese, Korean, Chilean and U.S. patents relating to zovegalisib and our U.S. and foreign patents relating to lirafugratinib, we do not own or in-license any issued patents relating to our platform or our product candidates under clinical development.

The research and development for certain of our programs was performed during the initial research term under the DESRES Agreement. Under the DESRES Agreement, D. E. Shaw Research controls the rights to its technology (including its supercomputer and software, each of which are important aspects of our Dynamo® platform), we control the rights to certain compounds, and we jointly own with D. E. Shaw Research any other work product created by D. E. Shaw Research and us. Subject to certain limits, we have the right to have the

following work product assigned to us: the composition of matter, method of use, and method of manufacture of certain compounds directed to a Category 1 Target, as set forth in the DESRES Agreement.

After any work product is assigned to us, we will have the right to prepare, file, prosecute and maintain patents that cover such assigned work product. We also have the implicit right to defend patents that cover work product owned by us.

To date, some of the work product created under our agreement with D. E. Shaw Research has been created by D. E. Shaw Research and us, together, and is thus initially co-owned. We have subsequently obtained sole ownership of certain intellectual property relating specifically to some of our clinical candidates. By virtue of inventorship, we initially jointly owned intellectual property rights pertaining to zovegalisib, but have subsequently obtained sole ownership of intellectual property rights relating to it and certain other PIK3CA inhibitors. Patent applications claiming a genus of PIK3CA inhibitor compounds remain jointly owned with D. E. Shaw Research. We have the first right to prepare, file, prosecute, maintain and defend patents that cover work product jointly created by D. E. Shaw Research and us. If we choose not to exercise those rights with respect to patents and patent applications that cover joint work product, D. E. Shaw Research will have the right to take over such activities, unless such rights are waived. The party that is preparing, filing, prosecuting and maintaining a patent that covers joint work product also has the right to enforce such patent against infringers. If we or D. E. Shaw Research fail to adequately protect any co-owned intellectual property, our ability to commercialize products could suffer.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation.

The degree of patent protection we require to successfully commercialize our product candidates may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our pending patent applications will issue, or that any of our pending patent applications that mature into issued patents will include claims with a scope sufficient to protect our product candidates under clinical development or our other product candidates. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally twenty years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. 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 commercialized. As a result, our owned patent portfolio and any patent portfolio we may license in the future may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar or identical to our product candidates, including generic versions of such products.

We have licensed patent rights, and in the future may license additional patent rights, to or from third parties, such as the license of our FGFR2 program, including lirafugratinib, to Elevar. These licensed patent rights may be valuable to our business, and we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or medicines underlying such licenses. We cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. If any such licensors or licensees fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated and our right to develop and commercialize any of our products that are the subject of such licensed rights could be adversely affected.

Other parties have developed technologies that may be related or competitive to our own, and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in our own patent applications, with respect to either the same methods or formulations or the same subject matter, in either case that we may rely upon to dominate our patent position in the market. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights cannot be predicted with any certainty.

In addition, the patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Further, with respect to most of the pending patent applications covering our product candidates, prosecution has yet to commence. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the U.S. Patent and Trademark Office, or USPTO, have been significantly narrowed by the time they issue, if at all. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license to or from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Even if we acquire patent protection that we expect should enable us to maintain such competitive advantage, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third-party submission of prior art to the USPTO challenging the priority of an invention claimed within one of our patents, which submissions may also be made prior to a patent's issuance, precluding the granting of any of our pending patent applications. We may become involved in opposition,

derivation, reexamination, inter parties review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others from whom we have obtained licenses to such rights.

Competitors may claim that they invented the inventions claimed in our issued patents or patent applications prior to us, or may file patent applications before we do. Competitors may also claim that we are infringing on their patents and that we therefore cannot practice our technology as claimed under our patents, if issued. Competitors may also contest our patents, if issued, by showing the patent examiner that the invention was not original, was not novel or was obvious. In litigation, a competitor could claim that our patents, if issued, are not valid for a number of reasons. If a court agrees, we would lose our rights to those challenged patents.

In addition, we may in the future be subject to claims by our former employees, collaborators, vendors, partners, or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we generally require all of our employees, consultants and advisors and any other third parties who have access to our proprietary know-how, information or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. With respect to intellectual property arising in the course of our collaboration with D. E. Shaw Research, disagreements between us and D. E. Shaw Research may impact our exclusive control of intellectual property important for protecting our product candidates and proprietary position. A loss of exclusivity, in whole or in part, could allow others to compete with us and harm our business.

An adverse determination in any such submission or proceeding 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, without payment to us, or could limit the duration of the patent protection covering our technology and product candidates. Such challenges may also result in our inability to manufacture or commercialize our product candidates without infringing third party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if they are unchallenged, our owned patent portfolio and any patent portfolio we may license in the future may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. For example, a third party may develop a competitive product that provides benefits similar to one or more of our product candidates but that has a different composition that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business.

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.

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 process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional 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, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our product candidates, which would have a material adverse effect on our business.

Our failure to secure trademark registrations could adversely affect our business and our ability to market our products and product candidates.

Our trademark applications in the United States and any other jurisdictions where we may file may not be allowed for registration, and our registered trademarks may not be maintained or enforced. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in corresponding foreign agencies, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our applications and/or registrations, and our applications and/or registrations may not survive such proceedings. Failure to secure such trademark registrations in the United States and in foreign jurisdictions could adversely affect our business and our ability to market our products and product candidates.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed.

In addition to the protection afforded by patents, we rely upon unpatented trade secret protection, unpatented know-how and continuing technological innovation to develop and maintain our competitive position. With respect to the building of our proprietary compound library, we consider trade secrets and know-how to be our primary intellectual property. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our collaborators, scientific advisors, employees and consultants, and invention assignment agreements with our consultants and employees. We may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements, however, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

Our trade secrets could otherwise become known or be independently discovered by our competitors. Competitors could purchase our product candidates and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If our trade secrets are not adequately protected so as to protect our market against competitors' products, our competitive position could be adversely affected, as could our business.

Risks Related to Intellectual Property Litigation

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability and the ability of our licensee or collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and frequent litigation regarding patents and other intellectual property rights. We may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, including interference proceedings before the USPTO. Our competitors or other third parties may assert infringement claims against us, alleging that our products or technologies are covered by their patents. Given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. Many companies have filed, and continue to file, patent applications related to PI3K inhibitors and FGFR2 inhibitors. Some of these patent applications have already been allowed or issued, and others may issue in the future. Since these areas are competitive and of strong interest to pharmaceutical and biotechnology companies, there will likely be additional patent applications filed and additional patents granted in the future, as well as additional research and development programs expected in the future. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates, or the practice of our technology. If a patent holder believes our product or product candidate infringes on its patent, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant product revenue and against whom our owned patent portfolio and any patent portfolio we may license in the future may thus have no deterrent effect.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our product candidates and technology. We may choose to obtain a license, even in the absence of an action or finding of infringement. In either case, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be granted on non-exclusive terms, thereby providing our competitors and other third parties access to the same technologies licensed to us. Without such a license, we could be forced, including by court order, to cease developing and commercializing the infringing technology or product candidates. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed such third-party patent rights. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. If we lose a foreign patent lawsuit, alleging our infringement of a competitor's patents, we could be prevented from marketing our products in one or more foreign countries, which would have a materially adverse effect on our business.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may in the future be

subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate such technologies or features would have a material adverse effect on our business, and may prevent us from successfully commercializing our product candidates. In addition, we may lose valuable intellectual property rights or personnel as a result of such claims. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product candidates, which would have an adverse effect on our business, results of operations and financial condition.

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

Competitors and other third parties may infringe, misappropriate or otherwise violate our patents and other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims. A court may disagree with our allegations, however, and may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the third-party technology in question. Further, such third parties could counterclaim that we infringe their intellectual property or that a patent we have asserted against them is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace. In addition, third parties may initiate legal proceedings against us to assert such challenges to our intellectual property rights. The outcome of any such proceeding is generally unpredictable. 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. Patents may be unenforceable if someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. It is possible that prior art of which we and the patent examiner were unaware during prosecution exists, which could render any patents that may issue invalid. Moreover, it is also possible that prior art may exist that we are aware of but do not believe is relevant to our future patents, should they issue, but that could nevertheless be determined to render our patents invalid.

An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. If a defendant were to prevail on a legal assertion of invalidity or unenforceability of our patents covering one of our product candidates, we would lose at least part, and perhaps all, of the patent protection covering such product candidate. Competing products may also be sold in other countries in which our patent coverage might not exist or be as strong.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. 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 adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Risks Related to Enforcement of Our Intellectual Property Rights

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

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly in developing countries. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, the patent laws of some foreign countries do not afford intellectual property protection to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other

intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. 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, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in the major markets for our product candidates, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent 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. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

Risks Related to Third Party Intellectual Property

We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our products. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially. Although we believe that licenses to these patents are available from these third parties on commercially reasonable terms, if we were not able to obtain a license, or were not able to obtain a license on commercially reasonable terms, our business could be harmed, possibly materially.

If we fail to comply with our obligations in the agreements under which we collaborate with or license intellectual property rights from third parties, or otherwise experience disruptions to our business relationships with our collaborators or licensors, we could lose rights that are important to our business.

We expect our future license agreements will impose various development, diligence, commercialization, and other obligations on us in order to maintain the licenses. In spite of our efforts, a future licensor might conclude that we have materially breached our obligations under such license agreements and seek to terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patent rights licensed thereunder fail to provide the intended exclusivity, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization of certain of our product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;

- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and

- the priority of invention of patented technology.

The agreements under which we may license intellectual property or technology from third parties may be 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 licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

These and similar issues may arise with respect to our collaboration agreements, such as our DESRES Agreement, as amended. While the initial research term has ended under the DESRES Agreement, there can be no assurance that a dispute between the parties will not arise. These disputes may involve ownership or control of intellectual property rights, exclusivity obligations, diligence and payment obligations, for example.

Under the DESRES Agreement, D. E. Shaw Research controls the rights to its technology, we control the rights to certain compounds, and we jointly own with D. E. Shaw Research any other work product created by D. E. Shaw Research and us. Any work product we jointly own with D. E. Shaw Research and any other information that we or D. E. Shaw Research share is subject to a non-exclusive cross-license between us and D. E. Shaw Research, subject to certain exceptions. In some instances, D. E. Shaw Research is required to assign to us some of the work product created by D. E. Shaw Research. Disputes may arise between us and D. E. Shaw Research, as well as any licensees or future potential collaborators, regarding intellectual property subject to the DESRES Agreement. If disputes over intellectual property that we co-own or we own individually prevent or impair our ability to maintain our current licensing or collaboration arrangements on acceptable terms, or undermine our ability to successfully control the intellectual property necessary to protect our product candidates, we may be unable to successfully develop and commercialize the affected product candidates. Uncertainties or disagreements around our rights under any such intellectual property may undermine our ability to partner our programs with third parties.

In addition, the DESRES Agreement is complex and certain provisions may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could be adverse to us, for example by narrowing what we believe to be the scope of our rights to certain intellectual property, or increasing what we believe to be our financial or other obligations under the DESRES Agreement, and any such outcome could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Intellectual Property Laws

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or Leahy-Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the Leahy-Smith Act has transformed the U.S. patent system into a "first to file" system. The first-to-file provisions, however, only became effective on March 16, 2013. Accordingly, it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and 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 harm our business, results of operations and financial condition.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce rights in our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing

patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce any patents that we may obtain in the future.

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to our product candidates or utilize similar technology but that are not covered by the claims of the patents that we license or may own;
- we or our licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or own now or in the future;
- we or our licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our present or future pending patent applications (whether owned or licensed) 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 or other third parties;
- 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 may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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 Government Regulation

Risks Related to Regulatory Approval

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, and our product candidates, if approved, could be subject to post-market study requirements, marketing and labeling restrictions, and even recall or market withdrawal if unanticipated safety issues are discovered following approval, which may result in significant additional expense.

If the FDA or a similar foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and listing, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval and applicable product tracking and tracing requirements. Additionally, under FDORA, sponsors of approved drugs must provide six months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing studies, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;

- clinical trial holds;
- fines, warning letters or other regulatory enforcement action;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about approved prescription drug products. In particular, while the FDA permits the dissemination of truthful and non-misleading information about an approved product, a manufacturer may not promote a product for uses that are not approved by the FDA. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of regulated products for off-label uses and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees, corporate integrity agreements or permanent injunctions under which specified promotional conduct must be changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Data collection is governed by restrictive regulations governing the processing and cross-border transfer of personal information and we may be subject to various federal, state-specific and international privacy laws. Failure to comply with such requirements in jurisdictions or states where we may conduct ongoing or future clinical trials could have a material adverse effect on our business, financial condition or results of operations.

As we conduct ongoing or future clinical trials, we may be subject to additional data collection and processing restrictions. Privacy and data security have become significant issues in the U.S., Europe and in many other jurisdictions where we conduct or may in the future conduct our operations. The regulatory framework for the collection, use, safeguarding, sharing and transfer of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. For example, the collection, use, storage, disclosure, transfer, or other processing of personal data of individuals in the EEA, including personal health data, is subject to the GDPR. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to having a legal basis for processing personal data, stricter requirements relating to the processing of sensitive data (such as health data), where required by GDPR, obtaining consent of the individuals to whom personal data relates, providing notice to the individuals to whom the personal data relates regarding data processing activities, implementing safeguards to protect the privacy and security of personal data, implementing processes to handle requests from individuals to exercise their data protection rights, maintaining records of our processing activities and to document data protection impact assessments where there is high risk processing, providing notification of data breaches in certain circumstances, and taking certain measures when engaging third-party processors or sub-processors. The GDPR focuses on accountability of controllers (such as us) and requires us to put in place all technical and organizational measures (privacy by design and by default) to ensure that we meet our obligations. Penalties under the GDPR include fines of up to €10,000,000 or 2% of our total worldwide annual revenue for certain comparatively minor offenses, or up to €20,000,000 or 4% of our total worldwide annual revenue for more serious offenses. EEA Member States have adopted implementing national laws to implement the GDPR which may partially deviate from the GDPR, and the competent authorities in the EEA Member States may interpret GDPR obligations slightly differently from country to country, so we do not expect to operate in a uniform legal landscape in the EU.

Further to the UK's exit from the EU on January 31, 2020, the UK incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law, referred to as the UK GDPR. The UK GDPR and the UK Data Protection Act 2018, or collectively, UK GDPR, set out the UK's data protection regime, which is independent from but currently still aligned to the EU's data protection regime. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. Although the UK is regarded as a third country under the EU's GDPR, the UK is recognized as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted, or the UK Adequacy Decision. Likewise, the UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. The UK Government introduced a Data Protection and Digital Information Bill, or Data Protection Bill, into the UK legislative process. The aim of the Data Protection Bill was to reform the UK's data protection regime following Brexit. The Data Protection Bill failed in the UK legislative process. A new Data (Use and Access) Bill, or the UK Bill, has been introduced into parliament. If passed, the final version of the UK Bill may have the effect of further altering the similarities between the UK and EEA data protection regime and

threaten the UK Adequacy Decision from the European Commission, or EC. This may lead to additional compliance costs and could increase our overall risk. The respective provisions and enforcement of the EU GDPR and UK GDPR may further diverge in the future and create additional regulatory challenges and uncertainties.

The GDPR imposes strict rules on the transfer of personal data out of the EEA and UK to the U.S. or other regions that have not been deemed to offer "adequate" privacy protections. On June 4, 2021, the EC issued new forms of standard contractual clauses, or SCCs, for data transfers from controllers or processors in the EEA (or otherwise subject to the EU GDPR) to controllers or processors established outside the EEA (and not subject to the EU GDPR). The new SCCs replace the SCCs that were adopted previously under the Data Protection Directive. The UK is not subject to the EC's new SCCs but has published its own standard clauses, the International Data Transfer Agreement, which enables transfers from the UK. We will be required to continue implementing these safeguards in the event we use these safeguards as our basis for conducting restricted data transfers under the EU GDPR and UK GDPR and doing so may require significant effort and cost. If relying on the SCCs or UK IDTA for data transfers, we may also be required to carry out transfer impact assessments to assess whether the recipient is subject to local laws which allow public authority access to personal data.

In July 2023, the European Commission adopted its adequacy decision for the EU-U.S. Data Privacy Framework, or the Framework, the successor of the EU-U.S. Privacy Shield framework. On the basis of the new adequacy decision, personal data can flow safely from the EU to U.S. companies participating in the Framework, without having to put in place additional data protection safeguards. There has been an extension to the Framework to cover UK and Swiss transfers to the U.S. The Framework could be challenged like its predecessor frameworks. This complexity and the additional contractual burden could increase our overall risk exposure. There may be further divergence in the future, including with regard to administrative burdens. However, the long term validity of the Framework, which has already been challenged in court, remains uncertain.

In connection with any clinical trials in Europe, we are subject to the supervision of local data protection authorities in those jurisdictions where we are monitoring the behavior of individuals in the EEA or UK (i.e., undertaking clinical trials). If we are investigated by an EEA or UK data protection authority, we may face fines and other penalties. Any such investigation or charges by EU or UK data protection authorities could have a negative effect on our business and on our ability to commercialize our products in the future, including with EU, UK-based or multi-national pharmaceutical partners.

Further, regulators and legislators in the U.S. are increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, Executive Order 14117, Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern, as implemented by Department of Justice regulations issued in December 2024, prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to countries of concern, including China. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. Actual or alleged violations of these regulations may be punishable by criminal and/or civil sanctions and may result in exclusion from participation in federal and state programs.

In addition to cross-border data protection requirements, we may be subject to various privacy laws in the United States at the state and federal level. In the United States, at the state level, for example, California Consumer Privacy Act, or CCPA, imposed a comprehensive privacy framework for covered businesses, which included an expanded definition of personal information, data privacy rights for consumers in the State of California, special rules on the collection of consumer data from minors, and provided substantial fines for non-compliance and, in some cases, a private right of action to consumers who are victims of data breaches involving their unredacted or unencrypted personal information. In addition, the California Privacy Rights Act, or CPRA, came into effect on January 1, 2023 and has expanded the privacy protections of the CCPA to also apply to personal information collected in a business to business capacity and from employment applicants, employees and former employees. The CPRA significantly modified the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The effects of the CCPA are potentially significant and may require us to modify our data collection or processing practices and policies and to incur substantial costs and expenses in an effort to comply and increase our potential exposure to regulatory enforcement and/or litigation. Furthermore, a number of other states have either proposed or enacted comprehensive consumer privacy laws similar to the CCPA, many of which vary in complexity and may be interpreted and enforced differently, thus potentially complicating our compliance efforts. In Washington, for example, the My Health My Data Act, or MHMDA, entered into force on March 31, 2024, and includes a broad private right of action. Seventeen other states passed privacy legislation, which will come into force over the next several years. While these laws generally have exceptions for protected health information that is subject to HIPAA and for information collected in the context of clinical trials, they may nevertheless impact our business activities.

There are also states that are specifically regulating health information or other specific types of information. For example, Connecticut and Nevada have passed similar laws regulating consumer health data. In addition, other states have proposed and/or passed legislation that regulates the privacy and/or security of certain specific types of information. For example, a small number of states, such as Illinois and Texas, have passed laws that regulate biometric data specifically. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and

distribution of our product candidates, if approved. State laws are changing rapidly and there is discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we may likely become subject, if enacted.

All of these evolving compliance and operational requirements may impose significant costs, such as costs related to organizational changes, implementing additional data protection measures and technologies, training employees, and engaging consultants and legal advisors, which costs may be likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, utilize management's time, and/or divert resources from other initiatives and projects. The increasing number and complexity of regional, country, and U.S. state data protection laws, and other changes in laws or regulations across the globe, especially those associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could lead to litigation or government investigations or enforcement actions and significant penalties against us and could have a material adverse effect on our business, financial condition, or results of operations.

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

We may use and integrate artificial intelligence into our business processes, and this innovation presents risks and challenges that could affect its adoption and, therefore, our business. The use of certain artificial intelligence technology can give rise to intellectual property risks, including compromises to proprietary intellectual property and intellectual property infringement. Additionally, we expect to see increasing government and supranational regulation related to artificial intelligence use and ethics, which may also significantly increase the burden and cost of research, development, and compliance in this area. For example, the EU's Artificial Intelligence Act, or the EU AI Act, — the world's first comprehensive artificial intelligence law — entered into force in June 2024 and, with some exceptions, becomes effective 24 months thereafter. This legislation imposes significant obligations on providers and deployers of high risk artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. Likewise, in the U.S., the regulatory environment is complex and uncertain. President Trump's Executive Order "Ensuring a National Policy Framework for Artificial Intelligence," effective December 11, 2025, tasks the U.S. Department of Justice with reviewing state laws regulating artificial intelligence, and instructs the Department of Commerce to develop a national artificial intelligence strategy. At the same time, several states, including Colorado and California, passed laws that regulate various facets of artificial intelligence, some of which have taken effect and will continue to take effect through 2026 and beyond. These laws address a wide range of artificial intelligence-related topics, including consequential decisions, transparency, training data, among others, and it remains unclear which requirements, if any, will be superseded by the Executive Order. In addition, there continues to be uncertainty regarding the application of existing federal and state legal frameworks to uses and development of artificial intelligence, and legal norms and market standards regarding artificial intelligence continue to evolve. For example, various federal and state regulators have issued guidance and focused enforcement efforts on the use of AI in regulated sectors. The FDA, for example, issued guidance on the use of artificial intelligence in medical devices, requiring detailed risk management and review processes to obtain approvals. In the future, if we develop or use artificial intelligence systems that are governed by the EU AI Act or any other artificial intelligence legislation in effect, it may necessitate ensuring higher standards of data quality, transparency, and human oversight, as well as adhering to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. We may also be subject to significant enforcement or litigation in the event of any perceived non-compliance.

Our vendors may in turn incorporate artificial intelligence tools into their offerings, and the providers of these artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, similar regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional nonclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In short, the foreign

regulatory approval process involves all of the risks associated with FDA approval. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we may intend to charge for our products will also be subject to approval.

If we are unable to successfully validate, develop and obtain regulatory approval for companion diagnostic tests for our product candidates that require or would commercially benefit from such tests, or experience significant delays in doing so, we may not realize the full commercial potential of these product candidates.

In connection with the clinical development of our product candidates for certain indications, we have previously engaged and may in the future engage third parties to develop or obtain access to *in vitro* companion diagnostic tests to identify patient subsets within a disease category who may derive selective and meaningful benefit from our product candidates. The FDA has indicated that if we continue zovegalisib in a specific biomarker-defined population, a companion diagnostic device will be required to ensure its safe and effective use. Such companion diagnostics would be used during our clinical trials as well as in connection with the commercialization of our product candidates. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. The FDA and similar foreign regulatory authorities regulate *in vitro* companion diagnostics as medical devices and, under that regulatory framework, will likely require the conduct of clinical trials to demonstrate the safety and effectiveness of any diagnostics we may develop, which we expect will require separate regulatory clearance or approval prior to commercialization.

We intend to rely on third parties for the design, development and manufacture of companion diagnostic tests for our therapeutic product candidates that may require such tests. In connection with such collaborative agreements, we will be dependent on the sustained cooperation and effort of our collaborators in developing and obtaining approval for these companion diagnostics. It may be necessary to resolve issues such as selectivity/specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics during the development and regulatory approval processes. Moreover, even if data from preclinical studies and early clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. We and our collaborators may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our therapeutic candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for these therapeutic product candidates, or experience delays in doing so, the development of these therapeutic product candidates may be adversely affected, these therapeutic product candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of these therapeutics that obtain marketing approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative 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.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates.

In June 2024, the U.S. Supreme Court overruled the Chevron doctrine, which gives deference to regulatory agencies' statutory interpretations in litigation against federal government agencies, such as the FDA, where the law is ambiguous. This decision may result in more lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, any of which could delay the FDA's review of our regulatory submissions. We cannot predict the full impact of this decision, future judicial challenges brought against the FDA, or the nature or extent of government regulation that may arise from future legislation or administrative action. 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.

Risks Related to Anti-bribery, Anti-corruption and Other Government Regulations

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop and implement costly compliance programs.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase in time. We have engaged and plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Although we do not currently have any products on the market, if we begin commercializing our product candidates, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and governments of foreign jurisdictions in which we conduct our business. Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product candidates for which we obtain marketing approval. See *"Business – Government Regulation – Other Healthcare Laws."*
Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities to be conducted by our sales team, were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, reputational harm, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, defending against any such actions can be costly and time consuming, and may require significant financial and 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. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

Risks Related to Regulatory Review of Certain Drug Development Designations

We may seek priority review designation for one or more of our product candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster regulatory review or approval process.

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months.

We may request priority review for our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily result in an expedited regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

We may seek orphan drug designation for certain of our product candidates and we may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

As part of our business strategy, we may seek orphan drug designation for certain of our product candidates, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the 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 200,000 or more 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 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.

Similarly, in the EU, the European Commission, upon the recommendation of the EMA's Committee for Orphan Medicinal Products, grants orphan designation in respect of a product if it can be shown that (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 the necessary investment in its development; 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. In the EU, orphan designation entitles a party to financial incentives such as reduction of fees or fee waivers.

Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same drug and approved use or indication for that time period, except in limited circumstances. The applicable period is seven years in the United States and ten years in the EU. The EU exclusivity period can be reduced to six years if, at the end of the fifth year, it is established that a product no longer meets the criteria for orphan designation, including if the product is sufficiently profitable so that market exclusivity is no longer justified. The European Commission introduced a legislative proposal in April 2023 that, if implemented, could reduce the current ten-year marketing exclusivity period in the EU for certain orphan medicines.

Even if we obtain orphan drug exclusivity for a drug, that exclusivity may not effectively protect the drug from competition because different drugs can be approved for the same approved use or indication. Even after an orphan drug is approved, the FDA can subsequently approve a later drug for the same approved use or indication if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan drug designation. 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 or if another drug with the same active moiety is determined to be safer, more effective, or represents a major contribution to patient care. 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. While we may seek orphan drug designation for certain of our product candidates, we may never receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations. In addition, the FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

Breakthrough therapy designation and fast track designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development, regulatory review or approval process, and each designation does not increase the likelihood that any of our product candidates will receive marketing approval in the United States.

In February 2026, we announced that the FDA granted breakthrough therapy designation to zovegalisib in combination with fulvestrant for the treatment of adults with PIK3CA mutant HR+/HER2- locally advanced or metastatic breast cancer following recurrence or progression on or after treatment with a CDK4/6 inhibitor. We may also seek a breakthrough therapy designation for some of our other product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to

make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

We may seek fast track designation for some of our product candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for fast track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures.

We may seek approval of our product candidates, where applicable, under the FDA's accelerated approval pathway. This pathway, even if granted for any of our current or future 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 in the United States.

We may seek accelerated approval of our current and/or future product candidates. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. Under FDORA, the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of approval for a product granted accelerated approval. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. FDORA also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit. Under FDORA, the FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress. In addition, the FDA currently requires, unless otherwise informed by the agency, pre-approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product. Thus, even if we do seek to utilize the accelerated approval pathway, we may not be able to obtain accelerated approval and, even if we do, we may not experience a faster development, regulatory review or approval process for that product. In addition, receiving accelerated approval does not assure that the product's accelerated approval will eventually be converted to a traditional approval.

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

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

Risks Related to Healthcare Legislative Reform

The FDA, the EMA and other regulatory authorities may implement additional regulations or restrictions on the development and commercialization of our product candidates, and such changes can be difficult to predict.

The FDA, the EMA and regulatory authorities in other countries have each expressed interest in further regulating biotechnology products. Agencies at both the federal and state level in the United States, as well as the U.S. Congressional committees and other governments or governing agencies, have also expressed interest in further regulating the biotechnology industry. Such action may delay or prevent commercialization of some or all of our product candidates. Adverse developments in clinical trials of products conducted by others may cause the FDA or other oversight bodies to change the requirements for approval of any of our product candidates. These regulatory review agencies and committees and the new requirements or guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory agencies and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and

could negatively impact our ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our current or future product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. See "*Business – Governmental Regulation – Current and future healthcare reform legislation.*"

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our current or future product candidates or additional pricing pressures. In particular, any policy changes through CMS as well as local state Medicaid programs could have a significant impact on our business in light of the higher proportion of SCD patients that utilize Medicare and Medicaid programs to pay for treatments. Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates.

In August 2022, the Inflation Reduction Act of 2022, or the IRA, was signed into law. The IRA includes several provisions that may impact our business, depending on how various aspects of the IRA are implemented. Provisions that may impact our business include a $2,000 out-of-pocket cap for Medicare Part D beneficiaries, the imposition of new manufacturer financial liability on most drugs in Medicare Part D, permitting the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, requiring companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delaying until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs were previously exempted from the Medicare drug price negotiation program; however, this exemption was restricted to drugs with only one orphan designation and for which the only approved indication is for that disease or condition. If a product received multiple orphan designations or had multiple approved indications, it would not qualify for the orphan drug exemption. Under the One Big Beautiful Bill Act of 2025, this restriction was eliminated; and effective for the 2028 initial price applicability year, all orphan drugs, regardless of the number of orphan drug designations or indications, are exempt from the Medicare drug price negotiation program. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. Although the effects of the IRA on our business and the healthcare industry in general are not yet known, we are taking into consideration the potential impact of the IRA on our development and commercialization activities.

On April 15, 2025, the Trump administration published Executive Order 14273, "Lowering Drug Prices by Once Again Putting Americans First," which generally directs the federal government to take measures to reduce drug prices, including eliminating the so-called "pill penalty" under the IRA that creates a distinction between small molecule and large molecule products for purposes of determining when a drug may be eligible for drug price negotiation. On May 12, 2025, the Trump administration published Executive Order 14297, "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients" which generally, among other things, directs the federal government to establish and communicate most-favored-nation price targets to pharmaceutical manufacturers to bring prices for American patients in line with comparably developed nations. Further, the Executive Order directs the federal government to support regulatory paths to allow direct-to-patient sales for companies that meet these targets. It also states that the Trump administration will take additional aggressive action (for example, examining whether marketing approvals should be modified or rescinded or opening the door for individual drug importation waivers) should manufacturers fail to offer American consumers the most-favored-nation lowest price. It also directs the Secretary of Commerce and the U.S. Trade Representative to "take all necessary and appropriate action to ensure foreign countries are not engaged in any act, policy, or practice that may be unreasonable or discriminatory or that may impair United States national security . . . including by suppressing the price of pharmaceutical products below fair market value in foreign countries." Notably, a similar Most Favored Nation, or MFN, pricing rule enacted under the first Trump administration was subject to an injunction resulting from judicial challenges to the rule, which was formally rescinded by the former Biden administration in August 2021.

On December 19, 2025, CMS released two proposed rules that would incorporate MFN pricing principles into federal reimbursement for prescription drugs. The first proposal, the Global Benchmark for Efficient Drug Pricing Model, or GLOBE for Medicare Part B, would require manufacturers of specified single source drugs and sole source biologics to pay incremental rebates based on international benchmark prices, with participation triggered for products meeting CMS's spending and eligibility criteria. The second proposal, the Guarding U.S. Medicare Against Rising Drug Costs, or GUARD, model for Medicare Part D, would similarly mandate manufacturer rebates for qualifying sole source drugs where the Medicare net price exceeds an MFN benchmark derived from international reference pricing methodologies. As proposed, GLOBE would begin a five year performance period on October 1, 2026 and GUARD would begin its performance period in 2027. These proposals will likely be subject to legal challenges that could delay their implementation or modify their impact on manufacturer pricing and revenue. Additionally, in November 2025, CMS introduced the GENErating cost Reductions fOr

U.S. Medicaid, or GENEROUS Model, a voluntary MFN framework for manufacturers participating in the Medicaid Drug Rebate Program. Although it is voluntary, the GENEROUS Model could also impact the drug pricing landscape for manufacturers.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our current or future product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

Recent federal legislation and actions by federal, state and local governments may permit reimportation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could materially adversely affect our operating results.

We may face competition in the United States for our development candidates and investigational medicines, if approved, from therapies sourced from foreign countries that have placed price controls on pharmaceutical products. In the United States, the Medicare Modernization Act, or MMA, contains provisions that call for the promulgation of regulations that expand pharmacists' and wholesalers' ability to import cheaper versions of an approved drug and competing products from Canada, where there are government price controls. Further, the MMA provides that these changes to U.S. importation laws will not take effect, unless and until the Secretary of the HHS certifies that the changes will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of products to consumers. On September 23, 2020, the Secretary of the HHS made such certification to Congress, and on October 1, 2020, FDA published a final rule that allows for the importation of certain prescription drugs from Canada. Under the final rule, States and Indian Tribes, and in certain future circumstances pharmacists and wholesalers, may submit importation program proposals to the FDA for review and authorization. On January 5, 2024, the FDA issued to Florida the first approval for a state importation plan. Several states now have pending applications with the FDA, including Colorado, Maine, New Hampshire, and New Mexico. If successfully implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any products that we may develop and adversely affect our future revenues and prospects for profitability. On September 25, 2020, CMS stated drugs imported by States under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. Separately, the FDA also issued a final guidance document outlining a pathway for manufacturers to obtain an additional National Drug Code, or NDC, for an FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country. The market implications of the final rule and guidance are unknown at this time. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any products that we may develop and adversely affect our future revenues and prospects for profitability.

Risks Related to the Regulatory Agency Review Process

Disruptions at the FDA, the SEC and other government agencies caused by funding shortages or global health concerns, in addition to substantial uncertainty regarding the Trump administration's initiatives and staffing cuts and how these might impact the FDA, its implementation of laws, regulations, policies and guidance, and its personnel, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or

otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

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

Disruptions at the FDA and other agencies, including leadership departures, personnel cuts, and policy changes, may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. Changes and cuts in FDA staffing have been reported within the pharmaceutical industry as creating instances of delays in the FDA's responsiveness or in its ability to review investigational new drug, or IND, submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. For example, over the last several years the U.S. government has shut down several times such as in October 2025 and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical government employees and stop critical activities. A prolonged government shutdown, significant leadership, personnel, and/or policy changes, or substantial modification in agency activities (including due to global health concerns or geopolitical factors) could significantly impact the ability of the FDA or other regulatory authorities to conduct their regular inspections, reviews, or other regulatory activities. A prolonged shutdown 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, including INDs placed on clinical holds or delayed new drug approvals. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

With the changes being implemented by the Trump administration beginning in 2025, there is substantial uncertainty as to the extent and how the Trump administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates and any products for which we obtain approval. This uncertainty could present new challenges and/or opportunities as we navigate development and approval of our product candidates. Some of these efforts have manifested to date in the form of personnel cuts and measures that could impact the FDA's ability to hire and retain key personnel, which could result in delays or limitations on our ability to obtain guidance from the FDA on our product candidates in development and obtain the requisite regulatory approvals in the future. There remains general uncertainty regarding future activities. The Trump administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of new therapeutic products. Alternatively, state governments may attempt to address or react to changes at the federal level with changes to their own regulatory frameworks in a manner that is adverse to our operations. If we become negatively impacted by future governmental orders, regulations, policies or guidance as a result of the Trump administration, there could be a material adverse effect on us and our business.

Risks Related to Employee Matters and Managing Growth

Risks Related to Employee Matters

Our future success depends on our ability to retain key executives and experienced scientific and clinical personnel to attract, retain and motivate qualified personnel.

We are highly dependent on the research and development, clinical and business development expertise of the principal members of our management, scientific and clinical team. Although we have entered into employment letter agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. 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 business strategy will be limited.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees, including temporary loss due to illness, could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. 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 successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel.

In particular, we have experienced a very competitive hiring environment in Cambridge, Massachusetts, where we are headquartered. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances

for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success with which we can discover and develop product candidates and our business will be limited.

Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical or other nonclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but 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 these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

The increasing use of social media platforms presents risks and challenges.

We and our employees utilize social media tools as a means of communication externally. Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our product candidates, operations, or business may cause us to be found in violation of applicable legal or contractual requirements. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, collaboration partners, and others, and which could have an adverse effect on our business, financial conditions, and results of operations. Furthermore, negative posts or comments about us or our product candidates in social media could seriously damage our reputation, brand image, and goodwill.

In addition, it is possible for individuals or groups to target companies with disruptive social media campaigns related to a request for access to unapproved drugs for patients with significant unmet medical need. If we experience a similar social media campaign regarding our decision to provide or not provide access to our product candidates under an expanded access policy, our reputation may be negatively affected and our business may be harmed.

Environmental, social, and governance matters may impact our business and reputation.

In addition to the changing rules and regulations related to environmental, social and governance, or ESG, matters imposed by governmental and self-regulatory organizations, a variety of third-party organizations, institutional investors and customers evaluate the performance of companies on ESG topics, and the results of these assessments are widely publicized. These changing rules, regulations and stakeholder expectations may result in increased general and administrative expenses and increased management time and attention spent complying with or meeting such regulations and expectations. Reduced access to or increased cost of capital may occur as financial institutions and investors increase expectations related to ESG matters.

Developing and acting on initiatives within the scope of ESG, and collecting, measuring and reporting ESG-related information and metrics can be costly, difficult and time consuming and is subject to evolving reporting standards. We may also communicate certain initiatives and goals, regarding environmental matters, diversity, social investments and other ESG-related matters, in our SEC filings or in other public disclosures. These initiatives and goals within the scope of ESG could be difficult and expensive to implement, the technologies needed to implement them may not be cost effective and may not advance at a sufficient pace, and we could be criticized for the accuracy, adequacy or completeness of the disclosure. Furthermore, statements about our ESG-related initiatives and goals, and progress against those goals, may be based on standards for measuring progress that are still developing, internal controls and processes that continue to evolve and assumptions that are subject to change in the future. In addition, we could be criticized for the scope or nature of such initiatives or goals, or for any revisions to these goals. If our ESG-related data, processes and reporting are incomplete or inaccurate, or if we fail to achieve progress with respect to our goals within the scope of ESG on a timely basis, or at all, our reputation, business, financial performance and growth could be adversely affected. In addition, in recent years "anti-ESG" sentiment has gained momentum across the U.S., with several states and Congress having proposed or enacted "anti-ESG" policies, legislation, or initiatives or issued related legal opinions, and the

President having recently issued an executive order opposing diversity equity and inclusion, or DEI, initiatives in the private sector. Such anti-ESG and anti-DEI-related policies, legislation, initiatives, litigation, legal opinions, and scrutiny could result in us facing additional compliance obligations, becoming the subject of investigations and enforcement actions, or sustaining reputational harm.

Risks Related to Growth and Acquisitions

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

As of December 31, 2025, we had 192 full-time employees. In the future, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of pharmaceutical and clinical development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the 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.

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

Our acquisitions expose us to risks that could adversely affect our business, and we may not achieve the anticipated benefits of acquisitions of businesses or technologies.

As a part of our business strategy, we may make selected acquisitions of complementary products and/or businesses. Any acquisition involves numerous risks and operational, financial, and managerial challenges, including the following, any of which could adversely affect our business, financial condition, or results of operations:

- difficulties in integrating new operations, technologies, products, and personnel;
- challenges maintaining uniform procedures, controls and policies with respect to our financial accounting systems;
- lack of synergies or the inability to realize expected synergies and cost-savings;
- underperformance of any acquired technology, product, or business relative to our expectations and the price we paid;
- negative near-term impacts on financial results after an acquisition, including acquisition-related earnings charges;
- the potential loss of key employees, customers, and strategic partners of acquired companies;
- claims by terminated employees and shareholders of acquired companies or other third parties related to the transaction;
- the assumption or incurrence of additional debt obligations or expenses, or use of substantial portions of our cash;
- the issuance of equity securities to finance or as consideration for any acquisitions that dilute the ownership of our stockholders;
- the issuance of equity securities to finance or as consideration for any acquisitions may not be an option if the price of our common stock is low or volatile which could preclude us from completing any such acquisitions;
- any collaboration, strategic alliance and licensing arrangement may require us to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us;
- diversion of management’s attention and company resources from existing operations of the business;
- inconsistencies in standards, controls, procedures, and policies;

- the impairment of intangible assets as a result of technological advancements, or worse-than-expected performance of acquired companies;

- assumption of, or exposure to, historical liabilities of the acquired business, including unknown contingent or similar liabilities that are difficult to identify or accurately quantify; and

- risks associated with acquiring intellectual property, including potential disputes regarding acquired companies' intellectual property.

In addition, the successful integration of acquired businesses requires significant efforts and expense across all operational areas. There can be no assurance that any of the acquisitions we may make will be successful or will be, or will remain, profitable. Our failure to successfully address the foregoing risks may prevent us from achieving the anticipated benefits from any acquisition in a reasonable time frame, or at all.

Risks Related to Business Disruptions

Our internal information technology systems, or those of our third-party collaborators and/or partners, may fail or suffer cybersecurity breaches, loss or leakage of data and other disruptions, which could result in a material disruption of our development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality, integrity, and availability of such information. We also have outsourced elements of our operations to third parties, and as a result we collaborate with a number of third-party CROs, vendors, and other contractors and consultants who have access to our confidential information.

We have implemented and maintain a cybersecurity risk management program that includes processes for the identification, assessment and mitigation of cybersecurity risks. Due to the size and complexity and the increasing amounts of confidential information that are maintained, our internal information technology systems and infrastructure and those of our third-party CROs, vendors and other contractors and consultants are potentially vulnerable to breakdown or other damage, service interruptions, system malfunction, natural disasters, terrorism and telecommunication and electrical failures, as well as cyber-attacks or security compromises, cybersecurity incidents, or data breaches from inadvertent or intentional actions by our employees, third-party CROs, vendors, contractors, consultants and/or third parties with whom we do business, or from cyber-attacks or security compromises, incidents, or data breaches by malicious third parties (including the deployment of harmful malware, ransomware, digital extortion, denial-of-service attacks, supply chain attacks, social engineering (including phishing attacks) and business email compromises, and other means to affect service reliability and threaten the confidentiality, integrity, availability, and security of systems, infrastructure or information), which may compromise our systems and infrastructure or those of our partners, third-party CROs, vendors, contractors, consultants and/or third parties with whom we do business, or lead to data leakage or compromise. If such an event were to occur, it could result in legal claims or proceedings, liability or financial loss under laws that protect the privacy of personal information, damage to our reputation, and interruptions in our operations, which could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, similar events relating to the information technology systems of our third-party collaborators who we rely on for the manufacture of our product candidates and to conduct clinical trials could also have a material adverse effect on our business.

The risk of a cybersecurity incident, breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, insider threats, foreign governments, and cyber threat actors, has generally increased as the frequency, persistence, intensity and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, nor may we be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched and can originate from a wide variety of sources, including insider threats and outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies, or generated using artificial intelligence. In addition, changes in how our employees work and access our systems, which began during the COVID-19 pandemic and continue today, when part of our workforce is working remotely, could also lead to opportunities for bad actors to launch cyber-attacks or for employees to cause inadvertent or intentional security risks or incidents. The prevalent use of mobile devices also increases the risk of data security incidents.

We are also subject to legal obligations concerning cyber security. For example, as a company handling employee information of individuals who reside in Massachusetts, we are required to comply with the Massachusetts Data Security Regulations (201 CMR 17.00), which require the development and implementation of a Comprehensive Written Information Security Program and the maintenance of specific information security protections.

While we have not directly experienced any material system failure, accident or cybersecurity incident or breach to date, like others in our industry we and our vendors have experienced, and may in the future continue to experience, threats and cybersecurity incidents and other attempts to disrupt or gain unauthorized access to our and our third-party vendors' information systems. We cannot guarantee that our data

protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, or cybersecurity incidents or breaches in or compromises of our systems or those of third-party CROs, vendors, contractors, consultants and/or third parties with whom we do business. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our privacy and data security obligations. Further, although we maintain liability insurance at levels that we believe are appropriate for our business, we cannot assure our investors that it will be sufficient in type or amount to cover us against all claims related to security compromises or breaches, cyberattacks and other related breaches. To the extent that any disruption or security compromises, cybersecurity incident, or data breach were to result in a loss of, or damage to, our systems, infrastructure, data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed, the further development and commercialization of our product candidates or any future product candidates could be hindered or delayed, we could be required to expend significant amounts of money and other resources to repair, remediate, or replace our information systems or networks, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. Furthermore, any failure or perceived failure by us or any third-party collaborators, service providers, contractors or consultants to comply with our privacy, confidentiality, data security or similar obligations to third parties, or any cybersecurity incidents or data breaches that result in the unauthorized access, use, acquisition, disclosure, release or transfer of confidential or sensitive information, including physician data, patient data, or any personally identifiable information, may result in governmental investigations, enforcement actions, regulatory fines, litigation or public statements against us, could cause third parties to lose trust in us or could result in claims by third parties asserting that we have breached our privacy, confidentiality, data security or similar obligations, any of which could have a material adverse effect on our reputation, business, financial condition or results of operations. Moreover, cybersecurity incidents and data breaches can be difficult to detect, and any delay in identifying or remediating them may lead to increased harm. While we have implemented data security measures intended to protect our information technology systems and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions, or cybersecurity incidents, or data breaches.

If we fail to comply with applicable environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures, and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. Compliance with applicable environmental, health and safety laws and regulations is expensive, and current or future environmental regulations may impair our business, prospects, financial condition or results of operations.

Our current operations are located in Massachusetts; however, we rely on third parties, including those that are located outside the United States, and we or the third parties upon whom we depend may be adversely affected by natural disasters or other unplanned events and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current operations are located in Massachusetts. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, geopolitical conflicts, power shortage, telecommunication failure or other natural or man-made accidents or incidents that result in us being unable to fully utilize our facilities, or the facilities of our third-party contract manufacturers or CROs, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations.

Natural disasters or pandemics similar to the COVID-19 pandemic could disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the facilities of our third-party contract manufacturers or CROs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure our investors that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities or the facilities of our third-party contract manufacturers or CROs are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be

harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Common Stock

Risks Related to Trading Our Common Stock

The trading price of our common stock historically has been volatile, which may affect the price at which you could sell any shares of our common stock. Securities class action or other litigation involving our company or members of our management team could also substantially harm our business, financial condition and results of operations.

The market price for our common stock historically has been volatile and could continue to be subject to wide fluctuations in response to various factors. Since shares of our common stock were sold in our initial public offering, or IPO, in July 2020 at a price of $20.00 per share, our stock price has fluctuated significantly, ranging from an intraday low of $1.78 to an intraday high of $64.37 through February 20, 2026. This volatility may affect the price at which you could resell the common stock. Our stock price is likely to continue to be volatile and subject to significant price and volume fluctuations in response to market and other factors, including the factors described below. The stock market in general and Nasdaq and the market for biopharmaceutical companies in particular, have experienced extreme volatility that has often been unrelated or disproportionate to the operating performance of these companies.

The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- results of clinical trials of our product candidates or those of our competitors;
- 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 product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares;
- variations in our financial results or those of companies that are perceived to be similar to us;
- 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.

In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We have been the target of and may in the future be the target of litigation brought by our stockholders. The outcome of such pending and potential litigation is uncertain. If any of our stockholders were to bring a lawsuit against us, even if the lawsuit is without merit, we could incur substantial costs defending the lawsuit. Although the results of lawsuits and claims cannot be predicted with certainty, defending against such claims could be costly and divert our management’s attention from other business concerns, which could seriously harm our business. Any litigation to which we become a party may result in an onerous or unfavorable judgment, or may be resolved with a monetary payment.

An active trading market for our common stock may not be sustained.

If an active market for our common stock does not continue, it may be difficult for our stockholders to sell their shares without depressing the market price for the shares or sell their shares at or above the prices at which they acquired their shares or sell their shares at the time they would like to sell. Any inactive trading market for our common stock may also impair our ability to raise capital to continue to fund our operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

Risks Related to Dividends

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

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

General Risk Factors

Risks Related to Insider Control

Our executive officers, directors, principal stockholders and their affiliates exercise significant control over our company, which will limit your ability to influence corporate matters and could delay or prevent a change in corporate control.

As of December 31, 2025, the holdings of our executive officers, directors, principal stockholders and their affiliates, represented beneficial ownership, in the aggregate, of approximately 55.4% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to influence our management and affairs and control the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation, or sale of all or substantially all of our assets. These stockholders may have interests, with respect to their common stock, that are different from those of our public market investors and the concentration of voting power among these stockholders may have an adverse effect on the price of our common stock. In addition, this concentration of ownership might adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

Risks Related to Tax

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the IRC, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in the ownership of its equity over a three year period), the corporation's ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income may be limited. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2025, we had federal net operating loss carryforwards of approximately $923.9 million, and our ability to utilize those net operating loss carryforwards could be limited by an "ownership change" as described above.

Tax reform legislation could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, or IRS, and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many changes have been made and changes are likely to continue to occur in the future.

Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof. You are urged to consult your tax advisor regarding the implications of potential changes in tax laws on an investment in our common stock.

Risks Related to Operating as a Public Company

We have incurred and will continue to incur significant costs as a result of operating as a public company, and our management has devoted and will continue to devote substantial time to compliance initiatives.

As a public company, we have incurred and expect to incur significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations may continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. We are required to include with our annual reports an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we have been and will continue to be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes 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 neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404 or that we will not be able to comply with the requirements of Section 404 in a timely manner. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In addition, if we are not able to continue to meet these requirements, we may not be able to remain listed on Nasdaq.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Risks Related to Our Charter and Bylaws

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Our fourth amended and restated certificate of incorporation, as amended, the Certificate of Incorporation, and our amended and restated bylaws, as amended, the Bylaws, contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of the stockholders may be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office, and special meetings of stockholders may not be called by any other person or persons;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds (2/3) of all outstanding shares of our voting stock then entitled to vote in the election of directors;

- a requirement of approval of not less than a majority of all outstanding shares of our voting stock to amend any bylaws by stockholder action and not less than two-thirds (2/3) of all outstanding shares of our voting stock to amend specific provisions of our Certificate of Incorporation; and

- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval, which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our Certificate of Incorporation and Bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our Bylaws designate specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Pursuant to our Bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for any state law claims for (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of or based on a breach of a fiduciary duty owed by any director, officer or other employee of ours to us or our stockholders; (3) any action asserting a claim pursuant to any provision of the Delaware General Corporation Law, our Certificate of Incorporation or our Bylaws; or (4) any action asserting a claim governed by the internal affairs doctrine, or the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our Bylaws further provide that unless we consent in writing to the selection of an alternative forum, the United States District Court for the District of Massachusetts shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the Federal Forum Provision. In addition, our Bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

We recognize that the Delaware Forum Provision and the Federal Forum Provision in our Bylaws may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the Commonwealth of Massachusetts. Additionally, the forum selection clauses in our Bylaws may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our stockholders. 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. The Court of Chancery of the State of Delaware and the United States District Court for the District of Massachusetts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

Risks Related to Securities Analysts

If securities analysts do not publish 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 will rely in part on the research and reports that industry or securities analysts publish about us or our business. If one or more of the analysts covering our stock downgrade their evaluations of our stock or publishes inaccurate or unfavorable research about our business, the trading price of our stock may decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cyber Risk Management and Strategy

We have implemented and maintain a cybersecurity risk management program that is aligned with the National Institute of Standards and Technology Cybersecurity Framework and includes processes for the identification, assessment, and mitigation of cybersecurity risks. This process is overseen by the Director of Development Operations, or the IT Director. It includes periodic security assessments, audits, and testing conducted internally and supported by targeted engagement with third parties. Our strategy incorporates Zero Trust principles and utilizes defense-in-depth technologies to monitor, identify, and mitigate risks. We supplement our internal capabilities by partnering with a Managed Detection and Response provider to ensure continuous monitoring of our environment. We maintain internal information security policies, including an incident response plan, which are reviewed by or at the direction of the IT Director and are updated periodically to reflect material changes and improvement in our information security practices. We have a process to assess and review the cybersecurity practices of third-party vendors and service providers prior to onboarding and periodically throughout the engagement, including through vendor questionnaires and contractual requirements, as appropriate.

Governance Related to Cybersecurity Risks

The IT Director oversees the administration of our cybersecurity risk management program and reports to the Senior Director, Head of IT or Senior Director of IT. The IT Director and Senior Director of IT roles are both held by individuals who each have over twenty years of professional information technology, or IT, management experience. The Senior Director of IT meets regularly with the Audit Committee to report on and discuss information security and technology risks to our business, including our cyber risk management programs, controls, and procedures. The Senior Director of IT and the Audit Committee also conduct a high-level review of the threat landscape facing our business, discuss risk mitigation strategies, and the prioritization of our remediation efforts.

The IT Director meets periodically with members of the Relay Information Security Council, or RISC, which is comprised of the Senior Director of IT and senior leaders from various functions, including finance, legal, human resources, corporate development, and research and development. The RISC provides input to the IT Director in connection with proposed cyber strategies as it relates to potential business impacts from new or proposed technologies and security solutions across the organization, including implementation strategies designed to address potential risks and disruptions to the business. In the event we or one of our business partners experiences a cybersecurity incident, the RISC is responsible for assisting in evaluating the incident, including whether any disclosure of the incident is required. The Senior Director of IT reports to the Audit Committee on cyber initiatives and implementation resulting from RISC discussions.

Through the Audit Committee, the Board of Directors is informed of: (i) security initiatives, (ii) existing and emerging cybersecurity risks, including cybersecurity incidents; and (iii) any disclosure obligations arising from any cybersecurity incidents. The Board of Directors oversees our general risk management strategy and the most significant risks facing our business, and is responsible for ensuring that appropriate risk mitigation strategies are implemented. To date, we have not experienced any cybersecurity threats or incidents that have materially affected or are reasonably likely to materially affect the company and its business strategy, results of operations, and/or financial condition.

Item 2. Properties.

Our corporate headquarters are located in Cambridge, Massachusetts.

We occupy approximately (a) 41,474 square feet of office and laboratory space at 60 Hampshire Street, Cambridge, Massachusetts 02139, the lease term for which expires on June 30, 2032, and (b) 12,190 square feet of office space in Building 300 at One Kendall Square, Cambridge, Massachusetts 02139, the lease term for which expires on February 28, 2030.

We believe our existing facilities are sufficient for our needs for the foreseeable future. To meet the future needs of our business, we may lease additional or alternate space, and we believe suitable additional or alternative space will 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, and other factors.

On December 18, 2024, David Hayes, or the Plaintiff, an alleged Relay Therapeutics stockholder, derivatively and on behalf of us as a nominal defendant, filed a complaint in the Court of Chancery of the State of Delaware, or the Court, captioned *Hayes v. Borisy, et al.* (C.A. No. 2024-1309-PAF), or the Derivative Complaint, against certain of our directors and officers, or the Defendants. The Derivative Complaint alleges that, in 2021, 2022, and 2023, the Defendants awarded the members of our Board of Directors excessive compensation.

The Derivative Complaint asserts claims for breach of fiduciary duty, unjust enrichment, waste of corporate assets, and breach of fiduciary duty of disclosure. The Derivative Complaint seeks a judgment against the Defendants declaring that Plaintiff may maintain the action on behalf of us and that he is an adequate representative of us; awarding to us the damages sustained as a result of the breaches of fiduciary duty and unjust enrichment alleged against the Defendants; directing us to take all necessary actions to reform and improve an effective system of corporate governance and internal procedures; awarding us restitution from the Defendants; ordering the Defendants to disgorge and pay to us or cancel all profits, benefits, and other compensation obtained; awarding Plaintiff costs and disbursements of the action, including reasonable attorneys', accountants', and experts' fees, costs, and expenses; and granting such other relief that the Court deems just and proper. On January 24, 2025, we, as nominal defendants, and the Defendants separately answered the complaint. The case is now in discovery. We are unable to predict the outcome, or the reasonably possible loss or range of loss, if any, related to this matter.

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.

Certain Information Regarding the Trading of Our Common Stock

Our common stock trades under the symbol "RLAY" on the Nasdaq Global Market and has been publicly traded since July 16, 2020. Prior to this time, there was no public market for our common stock.

Holders of Our Common Stock

As of February 2, 2026, there were approximately 30 holders of record of shares of our common stock. This number does not include stockholders for whom shares are held in "nominee" or "street" name.

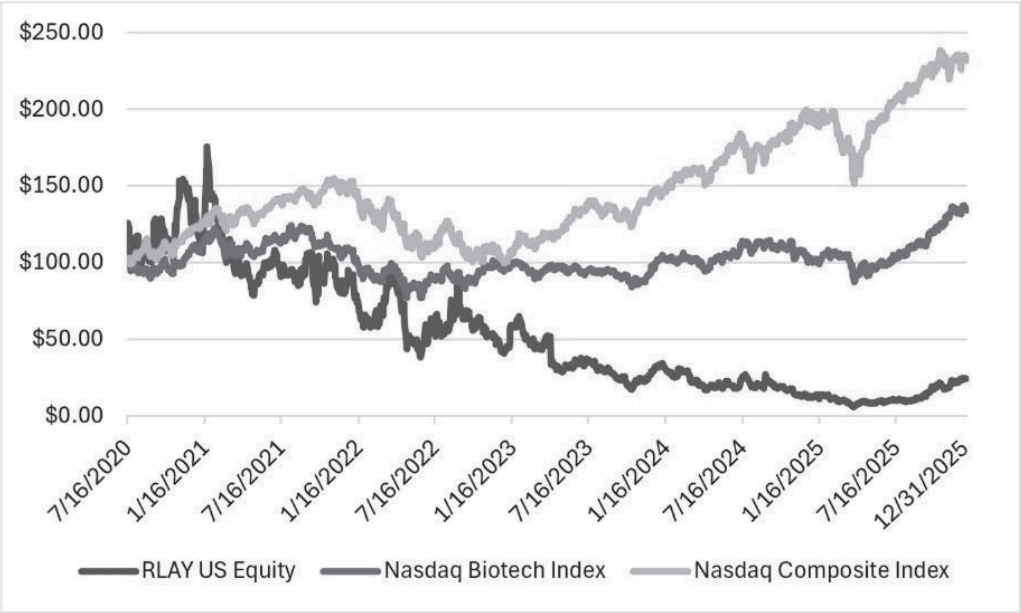
Dividends

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions, and other factors that our board of directors may deem relevant.

Stock Performance Graph

The following performance graph and related information shall not be deemed to be "soliciting material" or to be "filed" with the Securities and Exchange Commission, or SEC, for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, nor shall such information be incorporated by reference into any future filing under the Exchange Act or Securities Act of 1933, as amended, or the Securities Act, except to the extent that we specifically incorporate it by reference into such filing.

In July 2020, we issued 23,000,000 shares of our common stock in our IPO at a price of $20.00 per share. The following performance graph compares the performance of our common stock to the Nasdaq Composite Index and to the Nasdaq Biotechnology Index from July 16, 2020, the closing market price on the first trading day of our common stock, through December 31, 2025. The comparison assumes $100 was invested in our common stock and in each of the foregoing indices after the market closed on July 16, 2020 and it assumes reinvestment of dividends, if any. The stock price performance included in this graph is not necessarily indicative of, nor is it intended to forecast, future stock price performance.



Securities Authorized for Issuance Under Equity Compensation Plans

Information about our equity compensation plans will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

Unregistered Sales of Equity Securities and Use of Proceeds

None.

Recent Sales of Unregistered Equity Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10-K.

Item 6. [Reserved]

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations, and intentions. As a result of many factors, including those factors set forth in the "Risk Factors" section 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.

Overview

We are a clinical-stage, small molecule precision medicine company developing potentially life-changing therapies for patients living with cancer and genetic disease. Our Dynamo® platform integrates an array of leading-edge computational and experimental approaches designed to drug protein targets that have previously been intractable or inadequately addressed.

We have deployed our technology platform to build a pipeline of product candidates to address targets in precision medicine where there is clear evidence linking target proteins to disease and where molecular diagnostics can unambiguously identify relevant patients for treatment. We believe this approach will increase the likelihood of successfully translating a specific pharmacological mechanism into clinical benefit.

We are advancing a pipeline of medicine candidates to address targets in precision oncology and genetic disease, including zovegalisib (RLY-2608), our lead product candidate discussed below.

Zovegalisib (RLY-2608). Zovegalisib is the first known allosteric, pan-mutant and isoform-selective phosphoinostide 3 kinase alpha, or PI3Kα, inhibitor in clinical development. It is the lead program in our efforts to discover and develop mutant selective inhibitors of PI3Kα.

- ***Breast Cancer and Solid Tumors***

  - ReDiscover Trial. In December 2021, we dosed the first patient in a first-in-human clinical trial for zovegalisib, or the ReDiscover Trial. Since then, we have predominantly focused on evaluating zovegalisib in combination with fulvestrant for patients with HR+, HER2–, PI3Kα-mutated, locally advanced or metastatic breast cancer. We are also advancing triplet combination arms with zovegalisib, fulvestrant and cyclin dependent kinase 4/6, or CDK 4/6, inhibitors, or atirmociclib, the investigative selective-CDK4 inhibitor from Pfizer Inc., or Pfizer. In the second quarter of 2025, we initiated a global Phase 3 registrational study, or the ReDiscover-2 Trial, which is designed to evaluate the safety and efficacy of zovegalisib plus fulvestrant in PI3Kα-mutated, HR+/HER2- advanced breast cancer patients previously treated with a CDK4/6 inhibitor. The comparator arm in the ReDiscover-2 Trial is capivasertib plus fulvestrant. In February 2026, we announced that the FDA granted Breakthrough Therapy designation to zovegalisib in combination with fulvestrant for the treatment of adults with PIK3CA mutant HR+/HER2- locally advanced or metastatic breast cancer following recurrence or progression on or after treatment with a CDK4/6 inhibitor.

  - Clinical Data. In June 2025, we announced updated interim clinical data for the zovegalisib plus fulvestrant arm of the ReDiscover Trial with a data cut-off date of March 26, 2025, and in December 2025, we announced an efficacy subset analysis of interim clinical data for zovegalisib at the San Antonio Breast Cancer Symposium 2025 with a data cut-off date of October 15, 2025. We believe that while the clinical data from the ReDiscover Trial disclosed to date are preliminary, the data suggest differentiated interim efficacy signals in the specified patient population and support selective target engagement across doses and mutation types with an encouraging interim safety and tolerability profile.

- ***Vascular Anomalies***

  - ReInspire Trial. In the first quarter of 2025, we initiated the global Phase 1/2 clinical trial for zovegalisib in patients with PIK3CA-related overgrowth spectrum, or PROS, and vascular anomalies driven by PIK3CA mutations, or the ReInspire Trial. Enrollment is continuing in this clinical trial.

In addition to the programs mentioned above, we are progressing our NRAS-selective inhibitor, RLY-8161, to address NRAS-mutated solid tumors as well as our non-inhibitory chaperone for Fabry disease. We are also advancing early-stage discovery programs across both precision oncology and genetic diseases.

We were incorporated in May 2015. We have devoted substantially all of our resources to developing our product candidates, developing our innovative computational and experimental approaches on protein motion, building our intellectual property portfolio, business planning, raising capital, and providing general and administrative support for these operations. To date, we have principally financed our operations through private placements of preferred stock and common stock, convertible debt, and proceeds from public offerings of our common stock.

In December 2024, we and Elevar Therapeutics, Inc., or Elevar, entered into an exclusive global licensing agreement, or the Elevar Agreement, pursuant to which Elevar was granted global development and commercialization rights for lirafugratinib. Under the terms of the Elevar Agreement, we received $5.0 million upon execution, $3.4 million upon transfer of active pharmaceutical ingredient and other materials, and $7.0 million in milestone payments as of December 31, 2025. We are eligible to receive up to $488.0 million in regulatory and commercial milestone payments, as well as tiered royalties.

In September 2024, we completed a public offering, or the September 2024 Offering, of 32,857,143 shares of common stock, including the exercise in full of the underwriters' option to purchase an additional 4,285,714 shares, at an offering price of $7.00 per share. We received proceeds of $218.2 million, which was net of $11.8 million in underwriting discounts and other offering expenses.

In August 2024, we entered into a sales agreement, or the 2024 Sales Agreement, with TD Securities (USA) LLC, or TD Securities, pursuant to which we may offer and sell shares of our common stock having aggregate gross proceeds of up to $250.0 million from time to time in "at-the-market" offerings through TD Securities, as our sales agent. As of December 31, 2025, we have not sold any shares under the 2024 Sales Agreement.

In January 2024, we entered into a securities purchase agreement with Nextech Crossover I SCP for the private placement of 2,500,000 shares of common stock at $12.00 per share, or the Private Placement. We received $29.8 million in proceeds from the Private Placement, which were net of $0.2 million in offering expenses.

In December 2020, we entered into a global collaboration and license agreement with Genentech, Inc., a member of the Roche Group, or Genentech, for the development and commercialization of RLY-1971 (now referred to as migoprotafib, or GDC-1971), or the Genentech Agreement. Under the terms of the Genentech Agreement, we received $75.0 million in an upfront payment in 2021, as well as $45.0 million in milestone payments. Genentech elected to terminate the Genentech Agreement without cause, effective as of January 7, 2025, or the Termination Date. As of the Termination Date, we are no longer entitled to receive any further milestones or other payments due after the Termination Date. The parties also ceased to have any development or commercialization obligations as of the Termination Date and the licenses that we granted to Genentech pursuant to the Genentech Agreement ceased to be in effect as of the Termination Date. We will not continue development of migoprotafib.

Inflation generally affects us by increasing our employee-related costs and clinical trial expenses, as well as other operating expenses. Our financial condition and results of operations may also be impacted by other factors we may not be able to control, such as public health crises, global supply chain disruptions, uncertain global economic conditions, global trade disputes or political instability as further discussed in the section "Risk Factors" in this Annual Report on Form 10-K. We do not believe that such factors had a material adverse impact on our results of operations during the years ended December 31, 2025, 2024, and 2023.

Since our inception, we have incurred significant operating losses on an aggregate basis. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more of our current or future product candidates. Our net losses were $276.5 million, $337.7 million, and $342.0 million for the years ended December 31, 2025, 2024, and 2023, respectively. As of December 31, 2025, we had an accumulated deficit of $2.0 billion. These losses have resulted primarily from costs incurred in connection with research and development activities, licensing and patent investment, and general and administrative costs associated with our operations. We expect to continue to incur significant expenses, including the costs of operating as a public company, and generate significant operating losses for at least the next several years.

We anticipate that our expenses will increase substantially if and as we:

- conduct our current and future clinical trials of our lead product candidate;
- conduct additional preclinical research and development of our early-stage programs;
- initiate and continue research and preclinical and clinical development of our other product candidates;
- seek to identify additional product candidates;
- pursue marketing approvals for any of our product candidates that successfully complete clinical trials, if any;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- require the manufacture of larger quantities of our product candidates for clinical development and potentially commercialization;
- obtain, maintain, expand, and protect our intellectual property portfolio;
- acquire or in-license other drugs and technologies;

- hire and retain additional clinical, regulatory, quality, and scientific personnel;
- build out new facilities or expand existing facilities to support our ongoing development activity; and
- add operational, financial, and management information systems and personnel, including personnel to support our drug development, any future commercialization efforts, and our operations as a public company.

In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution.

As a result, we will need additional financing to support our continuing operations. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity or debt financings or other sources, which may include collaborations with third parties. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed, on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back, or discontinue the development or commercialization of one or more of our product candidates.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce or terminate our operations.

We believe our cash, cash equivalents, and investments of $554.5 million as of December 31, 2025 will enable us to fund our operating expenses and capital expenditure requirements into 2029. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. We will need to raise additional capital in the future to continue developing the drugs in our pipeline and to commercialize any approved drug. We may seek to obtain additional financing in the future through the issuance of our common stock, through other equity or debt financings, or through collaborations or partnerships with other companies. We may not be able to raise additional capital on terms acceptable to us, or at all, and any failure to raise capital as and when needed could compromise our ability to execute on our business plan.

Components of our Results of Operations

Revenue

To date, our revenue primarily consists of amounts related to the Genentech Agreement and Elevar Agreement.

Operating Expenses

Research and Development Expenses

Research and Development Expenses include:

- salaries, benefits, and other employee costs, including stock compensation expense, for personnel engaged in research and development functions;
- costs of outside consultants, including their fees, stock compensation, and related travel expenses;
- expenses incurred under agreements with contract research organizations, or CROs, contract manufacturing organizations, or CMOs, and other vendors that conduct our clinical trials and preclinical activities;
- costs of acquiring, developing, and manufacturing clinical trial materials, and lab supplies;
- costs related to compliance with regulatory requirements;
- impairment of any intangible assets capitalized upon the acquisition of in-process research and development assets; and
- facility costs, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance, and other supplies.

We do not allocate certain internal costs, facilities, or overhead costs to specific development programs.

We expense research and development costs as the services are performed or the goods are received. We recognize costs for certain development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data, such as patient enrollment, clinical site activations, or other information provided to us by our vendors and our clinical investigative sites. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our financial statements as prepaid expenses or accrued research and development expenses.

Our lead product candidate is in clinical development. We also have earlier stage programs across both precision oncology and genetic diseases. Costs incurred for these programs include costs incurred to support our discovery research and translational science efforts up to the initiation of first-in-human clinical development. Platform research and other research and development activities include costs that are not specifically allocated to active product candidates, including facilities costs, depreciation expense, and other costs. Employee expenses include salary, wages, stock compensation, and other costs related to our personnel, which are not allocated to specific programs or activities.

We cannot determine with certainty the duration and costs of future clinical trials and future development costs, if, when, or to what extent we will generate revenue from the commercialization and sale of any of our product candidates for which we obtain marketing approval or our other research and development costs. We may never succeed in obtaining marketing approval for any of our product candidates.

The duration, costs, and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

- the scope, rate of progress, expense, and results of our preclinical development activities, any future clinical trials of our lead product candidate, or other product candidates and other research and development activities that we may conduct;
- uncertainties in clinical trial design and patient enrollment or drop out or discontinuation rates;
- establishing an appropriate safety and efficacy profile with IND-enabling studies;
- the initiation and completion of future clinical trial results;
- the timing, receipt, and terms of any approvals from applicable regulatory authorities including the FDA and non-U.S. regulators;
- significant and changing government regulation and regulatory guidance;
- potential additional studies requested by regulatory agencies;
- establishing clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers in order to ensure that we or our third-party manufacturers are able to make product successfully;
- the impact of any business interruptions to our operations, including the timing and enrollment of patients in our planned clinical trials, or to those of our manufacturers, suppliers, or other vendors resulting from any public health crisis or ongoing geopolitical conflicts and related global economic sanctions;
- the expense of filing, prosecuting, defending, and enforcing any patent claims and other intellectual property rights; and
- maintaining a continued acceptable safety profile of our product candidates following approval, if any, of our product candidates.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect to continue to incur significant research and development expenses for the foreseeable future as we continue to conduct clinical trials of our lead product candidate, initiate clinical trials for our other product candidates, as well as identify and develop additional product candidates.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant trial delays due to patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development.

Change in Fair Value of Contingent Consideration Liability

Change in Fair Value of Contingent Consideration Liability consists of fluctuations in the estimated fair value of Contingent Milestone Payments, as well as changes in the recorded amounts of Contingent Earnout Payments, under the Merger Agreement with ZebiAI.

General and Administrative Expenses

General and Administrative Expenses primarily consist of salaries and other employee costs, including stock compensation, for personnel in our executive, finance, corporate, and business development and administrative functions. General and Administrative Expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax, and consulting services; other expenses associated with operating as a public company, including compliance with exchange listing and Securities and Exchange Commission, or SEC, requirements, director and officer insurance costs, and investor and public relations costs; travel expenses; and facility-related expenses, which include depreciation costs and allocated expenses for rent and maintenance of facilities.

We expect to continue to incur significant general and administrative expenses in the future and as we continue our research and development activities, as well as other activities related to the potential commercialization of our product candidates.

Other Income, Net

Other Income, Net primarily consists of interest income related to interest earned on our cash, cash equivalents, and investments.

Income Taxes

Since our inception in 2015, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in any year or for our earned research and development tax credits, due to our uncertainty of realizing a benefit from such items.

As of December 31, 2025, we had federal net operating loss carryforwards of $923.9 million, of which $43.1 million begin to expire in 2035 and $880.8 million do not expire.

As of December 31, 2025, we had state net operating loss carryforwards of $625.6 million, which begin to expire in 2035.

As of December 31, 2025, we had federal research and development tax credit carryforwards of $55.9 million, which begin to expire in 2035.

As of December 31, 2025, we had state research and development tax credit carryforwards of $29.9 million, which begin to expire in 2030.

As of December 31, 2025, we had federal orphan drug tax credit carryforwards of $17.0 million, which begin to expire in 2042.

Results of Operations

Comparison of years ended December 31, 2025 and 2024

The following table summarizes our results of operations for the years ended December 31, 2025 and 2024.

	Year Ended December 31,		Change
	2025	2024	
		(in thousands)	
License and other revenue	$ 15,355	$ 10,007	$ 5,348
Operating expenses:			
Research and development expenses	$ 261,383	$ 319,089	$ (57,706)
Change in fair value of contingent consideration liability	—	(13,206)	13,206
General and administrative expenses	56,710	76,592	(19,882)
Total operating expenses	318,093	382,475	(64,382)
Loss from operations	(302,738)	(372,468)	69,730
Other income, net	26,259	34,760	(8,501)
Net loss	$ (276,479)	$ (337,708)	$ 61,229

License and Other Revenue

During the year ended December 31, 2025, we recognized $15.4 million of license and other revenue from the Elevar Agreement, specifically in connection with the completion of each of our performance obligations thereunder in 2025, as well as receipt of certain milestone payments.

During the year ended December 31, 2024, we recognized $10.0 million of license and other revenue from the Genentech Agreement, specifically in connection with a milestone achieved thereunder in 2024.

Research and Development Expenses

The following summarizes our research and development expenses for the years ended December 31, 2025 and 2024:

	Year Ended December 31,		Change
	2025	2024	
		(in thousands)	
External costs for programs in clinical trials	$ 104,268	$ 92,096	$ 12,172
External costs for platform technologies and preclinical programs	38,526	76,392	(37,866)
Employee related expenses	95,581	123,601	(28,020)
Other expenses	23,008	27,000	(3,992)
Total research and development expenses	$ 261,383	$ 319,089	$ (57,706)

Research and development expenses were $261.4 million for the year ended December 31, 2025 compared to $319.1 million for the year ended December 31, 2024. The decrease of $57.7 million was primarily due to the series of strategic choices to streamline the research organization throughout 2024 and 2025, as well as decreases in costs incurred on continued development of lirafugratinib after execution of the Elevar Agreement in December 2024, offset by increases in costs related to the ReDiscover-2 Trial and ReInspire Trial.

Change in Fair Value of Contingent Consideration Liability

Change in fair value of our contingent consideration liability under the Merger Agreement with ZebiAI was $0 for the year ended December 31, 2025 compared to a decrease of $13.2 million for the year ended December 31, 2024. During the year ended December 31, 2024, the Contingent Milestone Payments and Contingent Earnout Payments were both reduced to $0. During the year ended December 31, 2025, there were no further changes to such amounts.

General and Administrative Expenses

General and administrative expenses were $56.7 million for the year ended December 31, 2025 compared to $76.6 million for the year ended December 31, 2024. The decrease of $19.9 million was primarily due to a decrease in stock compensation expense, as well as other employee costs, partially offset by costs to obtain the Elevar Agreement, which were expensed commensurate with the timing of revenue recognized during the year ended December 31, 2025.

Other Income, Net

Other income, net, was $26.3 million for the year ended December 31, 2025 compared to $34.8 million for the year ended December 31, 2024. The decrease of $8.5 million was primarily a result of changes in the amounts invested between periods, as well as fluctuations in interest rates.

Comparison of years ended December 31, 2024 and 2023

The following table summarizes our results of operations for the years ended December 31, 2024 and 2023:

	Year Ended December 31,		Change
	2024	2023	
		(in thousands)	
License and other revenue	$ 10,007	$ 25,546	$ (15,539)
Operating expenses:			
Research and development expenses	$ 319,089	$ 330,018	$ (10,929)
Change in fair value of contingent consideration liability	(13,206)	(6,422)	(6,784)
General and administrative expenses	76,592	74,950	1,642
Total operating expenses	382,475	398,546	(16,071)
Loss from operations	(372,468)	(373,000)	532
Other income, net	34,760	31,027	3,733
Net loss	$ (337,708)	$ (341,973)	$ 4,265

License and Other Revenue

During the year ended December 31, 2024, we recognized $10.0 million of license and other revenue from the Genentech Agreement, specifically in connection with a milestone achieved thereunder in 2024.

During the year ended December 31, 2023, we recognized $25.5 million of license and other revenue from the Genentech Agreement, specifically in connection with milestones achieved thereunder in prior years. Although the milestones were achieved in prior years, the variable consideration was previously constrained until 2023.

Research and Development Expenses

The following summarizes our research and development expenses for the years ended December 31, 2024 and 2023:

	Year Ended December 31,		Change
	2024	2023	
		(in thousands)	
External costs for programs in clinical trials	$ 92,096	$ 101,055	$ (8,959)
External costs for platform technologies and preclinical programs	76,392	76,471	(79)
Employee related expenses	123,601	125,471	(1,870)
Other expenses	27,000	27,021	(21)
Total research and development expenses	$ 319,089	$ 330,018	$ (10,929)

Research and development expenses were $319.1 million for the year ended December 31, 2024 compared to $330.0 million for the year ended December 31, 2023. The decrease of $10.9 million was primarily due to the impact of prioritization of certain programs in our pipeline, as previously disclosed in 2023 and 2024.

Change in Fair Value of Contingent Consideration Liability

The change in fair value of our contingent consideration liability for Contingent Milestone Payments under the Merger Agreement with ZebiAI was a decrease of $13.2 million for the year ended December 31, 2024 compared to a decrease of $6.4 million for the year ended December 31, 2023. During the year ended December 31, 2024, the Contingent Milestone Payments and Contingent Earnout Payments were both reduced to $0.

General and Administrative Expenses

General and administrative expenses were $76.6 million for the year ended December 31, 2024 compared to $75.0 million for the year ended December 31, 2023. The increase of $1.6 million was primarily due to an increase in stock compensation expense, partially offset by decreases in other employee compensation costs and certain other general and administrative expenses.

Other Income, Net

Other income, net, was $34.8 million for the year ended December 31, 2024 compared to $31.0 million for the year ended December 31, 2023. The increase of $3.7 million was primarily a result of changes in interest rates.

Liquidity and Capital Resources

As of December 31, 2025, we had cash, cash equivalents, and investments of $554.5 million.

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses. We have not yet commercialized any products and we do not expect to generate revenue from sales of any product candidates for several years, if ever. To date, we have principally financed our operations through private placements of preferred stock and common stock, convertible debt, and proceeds from public offerings of our common stock.

In December 2024, we entered into the Elevar Agreement, pursuant to which Elevar was granted global development and commercialization rights for lirafugratinib. As of December 31, 2025, we had received $5.0 million in upfront consideration, $3.4 million in conjunction with transfer of active pharmaceutical ingredient and other materials, and $7.0 million in milestone payments pursuant to the Elevar Agreement.

In September 2024, we completed the September 2024 Offering of 32,857,143 shares of common stock, including the exercise in full of the underwriters' option to purchase an additional 4,285,714 shares, at an offering price of $7.00 per share. We received proceeds of $218.2 million, which was net of $11.8 million in underwriting discounts and other offering expenses.

In August 2024, we filed a universal shelf registration statement on Form S-3ASR with the SEC, or the 2024 Shelf, to register for sale an amount of our common stock, preferred stock, debt securities, warrants and/or units in one or more offerings, which became effective upon filing with the SEC (File No. 333-281308). The 2024 Shelf replaced our prior universal shelf registration statement filed with the SEC in August 2021 (File No. 333-258768), which would have expired in August 2024.

In August 2021, we entered into the 2021 Sales Agreement with Cowen, pursuant to which we could offer and sell shares of our common stock having aggregate gross proceeds of up to $300.0 million from time to time in "at-the-market" offerings through Cowen, as our sales agent. In August 2024, the 2021 Sales Agreement was terminated by mutual agreement between us and Cowen. Through termination of the 2021 Sales Agreement, we sold 4,915,669 shares of common stock under the 2021 Sales Agreement, from which we received $48.2 million in proceeds, which were net of $1.2 million in commissions paid to Cowen and other offering expenses.

In August 2024, we also entered into the 2024 Sales Agreement with TD Securities, pursuant to which we may offer and sell shares of our common stock having aggregate gross proceeds of up to $250.0 million from time to time in “at-the-market” offerings through TD Securities, as our sales agent. As of December 31, 2025, we have not sold any shares under the 2024 Sales Agreement.

In January 2024, we entered into a securities purchase agreement with Nextech Crossover I SCP for the Private Placement. We received $29.8 million in proceeds from the Private Placement, which were net of $0.2 million in offering expenses.

Through the Termination Date, we received $120.0 million in upfront and milestone payments from Genentech pursuant to the Genentech Agreement.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	Year Ended December 31,		
	2025	2024	2023
		(in thousands)	
Cash used in operating activities	$ (235,455)	$ (249,107)	$ (300,316)
Cash provided by (used in) investing activities	192,799	(41,083)	257,634
Cash provided by financing activities	1,604	270,153	34,753
Net decrease in cash, cash equivalents, and restricted cash	$ (41,052)	$ (20,037)	$ (7,929)

Operating Activities

During the year ended December 31, 2025, we used $235.5 million of cash on operating activities, primarily resulting from our net loss of $276.5 million and cash used to fund changes in our operating assets and liabilities of $23.3 million, offset by non-cash charges of $64.3 million.

During the year ended December 31, 2024, we used $249.1 million of cash on operating activities, primarily resulting from our net loss of $337.7 million, offset by non-cash charges of $74.0 million and cash provided by changes in our operating assets and liabilities of $14.6 million.

During the year ended December 31, 2023, we used $300.3 million of cash on operating activities, primarily resulting from our net loss of $342.0 million and cash used to fund changes in our operating assets and liabilities of $32.5 million, offset by non-cash charges of $74.1 million.

Investing Activities

During the year ended December 31, 2025, net cash provided by investing activities was $192.8 million, consisting of $193.2 million proceeds from net maturities of investments, offset by $0.4 million for the acquisition of property and equipment.

During the year ended December 31, 2024, net cash used in investing activities was $41.1 million, consisting of $39.1 million in net purchases of investments and $2.0 million for the acquisition of property and equipment.

During the year ended December 31, 2023, net cash provided by investing activities was $257.6 million, consisting of $261.8 million in proceeds from net maturities of investments, offset by $4.1 million for the acquisition of property and equipment.

Financing Activities

During the year ended December 31, 2025, net cash provided by financing activities was $1.6 million, consisting of $1.6 million in proceeds from the exercise of stock options and purchases under our 2020 Employee Stock Purchase Plan, or ESPP.

During the year ended December 31, 2024, net cash provided by financing activities was $270.2 million, consisting of $265.9 million in net proceeds from the Private Placement, at-the-market offerings, and the September 2024 Offering, as well as $4.3 million in proceeds from the exercise of stock options and purchases under our ESPP.

During the year ended December 31, 2023, net cash provided by financing activities was $34.8 million, primarily consisting of $30.3 million in net proceeds from at-the-market offerings, as well as $4.5 million in proceeds from stock option exercises and purchases under our ESPP.

Funding Requirements

We expect to continue to incur significant expenses in connection with our ongoing clinical development activities related to our product candidates and the ongoing preclinical development activities of our other programs. In addition, we continue to incur additional costs associated with operating as a public company.

As of December 31, 2025, we had cash, cash equivalents, and investments of $554.5 million. We believe that our existing cash, cash equivalents, and investments will enable us to fund our operating expenses and capital expenditure requirements into 2029. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with the development of our product candidates, as well as our preclinical programs, and because the extent to which we may enter into collaborations with third parties for the development of our product candidates is unknown, we are unable to estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our future capital requirements will depend on many factors, including:

- the impact of any business interruptions to our operations, including the timing and enrollment of patients in our planned clinical trials, or to those of our manufacturers, suppliers, or other vendors, resulting from public health epidemics or outbreaks of infectious disease or ongoing geopolitical conflicts and related global economic sanctions;
- the scope, progress, results, and costs of our current and future clinical trials of our lead product candidate and additional preclinical research of our other programs;
- the scope, progress, results, and costs of drug discovery, preclinical research, and clinical trials for our other product candidates;
- the number of future product candidates that we pursue and their development requirements;
- the costs, timing, and outcome of regulatory review of our product candidates;
- our ability to establish and maintain licenses or collaborations on favorable terms, if at all;
- the success of any existing or future licenses or collaborations that we may enter into with third parties;
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates;
- the achievement of milestones or occurrence of other developments that trigger payments under any existing or future license or collaboration agreements, if any;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under any existing or future license or collaboration agreements, if any;
- the costs and timing of future commercialization activities, including drug sales, marketing, manufacturing, and distribution, for any of our product candidates for which we receive marketing approval, to the extent that such sales, marketing, manufacturing, and distribution are not the responsibility of any licensee or collaborator that we may have at such time;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;

- the costs of preparing, filing, and prosecuting patent applications, maintaining, and enforcing our intellectual property rights and defending intellectual property-related claims;

- our headcount growth and associated costs if and as we expand our business operations and our research and development activities; and

- the costs of operating as a public company.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive, and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval for any product candidates or generate revenue from the sale of any product candidate for which we may obtain marketing approval. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drugs that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Adequate additional funds may not be available to us on acceptable terms, or at all. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of these securities may include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a common stockholder. Additional debt or preferred equity financing, if available, may involve agreements that include restrictive covenants that may limit our ability to take specific actions, such as incurring debt, making capital expenditures, or declaring dividends, which could adversely impact our ability to conduct our business, and may require the issuance of warrants, which could potentially dilute your ownership interest.

If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technology, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or collaborations, strategic alliances or licensing arrangements with third parties when needed, we may be required to delay, limit, reduce, and/or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

Intellectual Property License

On June 15, 2020, we entered into an Amended and Restated Collaboration and License Agreement, or DESRES Agreement, with D. E. Shaw Research, LLC, or D. E. Shaw Research, extending the term and otherwise modifying the terms of the Collaboration and License Agreement originally entered into on August 17, 2016. Pursuant to the DESRES Agreement, the parties jointly conducted research efforts with the goal of identifying and developing product candidates. The initial research term under the DESRES Agreement ended on August 16, 2025, with the DESRES Agreement continuing thereafter on a target-by-target basis until all payment obligations have expired. We paid an annual collaboration fee of up to $9.9 million to D.E. Shaw Research until the end of the initial research term. Additionally, on a product-by-product basis, we have agreed to pay D. E. Shaw Research milestone payments upon the achievement of certain development and regulatory milestone events for products we develop under the DESRES Agreement that are directed to a Category 1 Target or any target that was a Category 1 Target. Such payments for achievement of development and regulatory milestones total up to $7.3 million in the aggregate for each of the first three products we develop and up to $6.3 million in the aggregate for each product we develop after the first three. In addition, we are obligated to pay D. E. Shaw Research royalty payments, as defined in the DESRES Agreement. We assessed the milestone and royalty events under the DESRES Agreement as of December 31, 2025 and 2024, concluding certain milestone payments were triggered as of December 31, 2025 and subsequently paid in January 2026 and no such payments were due as of December 31, 2024.

399 Binney Street

In December 2017, we executed an operating lease agreement for 44,336 square feet of office and laboratory space at 399 Binney Street, Cambridge, Massachusetts, which was increased to 44,807 square feet in January 2018. Pursuant to the terms of the operating lease agreement, as amended in November 2019 and September 2020, the operating lease was previously scheduled to expire on April 30, 2029. On June 3, 2025, we executed another amendment to the operating lease, as amended, pursuant to which termination was accelerated to July 3, 2025. We continued to be responsible for rent and other obligations under the operating lease, as amended, through July 3, 2025, at which point such obligations ceased and the operating lease was terminated.

60 Hampshire Street

In May 2021, we executed an operating lease agreement for 41,474 square feet of office and laboratory space at 60 Hampshire Street, Cambridge, Massachusetts 02139. We gained control of the space in July 2022 and the lease expires in June 2032. There are no renewal options. We provided a letter of credit in connection with the agreement in the amount of $1.2 million with a financial institution, which expires commensurate with the lease in June 2032.

Building 300 at One Kendall Square

In June 2025, we executed an operating leases agreement for 12,190 square feet of office space in Building 300 at One Kendall Square, Cambridge, Massachusetts 02139. We gained control of the space in July 2025 and the lease expires in February 2030. There are no renewal options. We provided a letter of credit in connection with the agreement in the amount $0.1 million with a financial institution, which expires commensurate with the lease in February 2030.

Other Significant Arrangements

We enter into contracts in the normal course of business with CROs and CMOs for clinical trials, preclinical research studies, and testing, manufacturing, and other services and products for operating purposes.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, costs, expenses, and the disclosure of contingent assets and liabilities in our 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 the notes 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.

Revenue Recognition

We account for revenue in accordance with Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers*, or ASC 606. In connection therewith, we recognize revenue when customers obtain control of promised goods or services in an amount that reflects the consideration we expect to receive in exchange for such goods or services.

Once a contract is determined to be within the scope of ASC 606, we assess the goods or services promised within the contract and determine those that are performance obligations at contract inception. We then determine the transaction price and allocate it to the performance obligations. As part of the accounting for such arrangements, we must use judgment to determine: (a) the number of performance obligations; (b) the transaction price, including the determination of whether milestones or other variable consideration should be included in the transaction price; and (c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of the transaction price.

We utilize key assumptions and judgments in (a) determining the stand-alone selling price for each performance obligation, which may include discounted cash flow models, evaluation of comparable transactions, and pricing considered in negotiating the transaction and estimated costs, and (b) determining how the transaction price is allocated amongst the performance obligations. We also use judgment to determine whether milestones or other variable consideration should be included in the transaction price. As part of management's evaluation of the transaction price, we consider numerous factors, including whether the achievement of the milestones is outside of our control, contingent upon the efforts of others, or subject to scientific risks of success. If we conclude it is probable that a significant revenue reversal would not occur, the associated milestone payment is included in the transaction price. Milestone payments that are not within our control, such as regulatory approvals, are generally not considered probable until those milestones are achieved. We re-evaluate the transaction price, including estimated variable consideration included in the transaction price and all constrained amounts, in each reporting period and as uncertain events are resolved or other changes in circumstances occur. For revenue-based royalties, including milestone payments based on the level of sales, we will include royalties in the transaction price at the later of (i) when the related sales occur or (ii) when the performance obligation to which some or all of the royalty is allocated has been satisfied (or partially satisfied).

Once the performance obligations are identified, the transaction price is allocated to each performance obligation based on the relative stand-alone selling price. We then recognize revenue for the amount of the transaction price allocated to the respective performance obligation when (or as) it is satisfied, either at a point in time or over time. If the performance obligation is satisfied over time, we recognize revenue based on the use of either an output or input method.

Prepaid and Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate prepaid and accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services performed on our behalf, and estimating the level of service performed and costs incurred for such services in comparison to

invoices and payments. The majority of our service providers invoice us in arrears for services performed on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. We make estimates of our prepaid and accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time.

Examples of estimated prepaid and accrued research and development expenses include fees paid to:

- CROs in connection with performing research activities on our behalf and conducting preclinical studies and clinical trials on our behalf;
- investigative sites or other service providers in connection with clinical trials;
- vendors in connection with preclinical and clinical development activities; and
- vendors related to product manufacturing and development and distribution of preclinical and clinical supplies.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CROs that conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of such agreements are subject to negotiation and vary from contract to contract, which 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 expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing fees, we estimate the time period over which services will be performed, enrollment of patients, number of sites activated, 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 prepaid expense or accrued expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates.

Recently Issued and Adopted Accounting Pronouncements

A description of recently issued accounting pronouncements that we have adopted is disclosed in Note 2, *Significant Accounting Policies*, to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. None of these pronouncements had a material impact on our financial position or results of operations.

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

Interest rate risk

We are exposed to market risk related to changes in interest rates of our investment portfolio of cash equivalents and short-term investments. As of December 31, 2025, our cash equivalents consisted of money market funds. As of December 31, 2025, our investments consisted of investments in U.S. treasury bills and United States agency securities that have contractual maturities of less than two years. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. The fair value of our marketable securities is subject to change as a result of potential changes in market interest rates, including changes in federal interest rates. The potential change in fair value for interest rate sensitive instruments has been assessed on a hypothetical 100 basis point adverse movement across all maturities. As of December 31, 2025, we estimate that such hypothetical 100 basis point adverse movement would not result in a material impact on our condensed consolidated results of operations.

As of December 31, 2025, we had no debt outstanding and, therefore, are not exposed to interest rate risk with respect to debt.

Foreign currency exchange risk

All of our employees and our operations are currently located in the United States and our expenses are generally denominated in U.S. dollars. However, we have entered into a limited number of contracts with vendors for research and development services that permit us to satisfy our payment obligations in U.S. dollars (at prevailing exchange rates), but have underlying payment obligations denominated in foreign currencies, including the Euro. We are subject to foreign currency transaction gains or losses on our contracts denominated in foreign currencies. To date, foreign currency transaction gains and losses have not been material to our financial statements and we have not had a formal hedging program with respect to foreign currency. We estimate that a 10% increase or decrease in current exchange rates would not have a material effect on our financial results for the years ended December 31, 2025, 2024, and 2023. While we have not engaged in the hedging of our foreign currency transactions to date, we are evaluating the costs and benefits of initiating such a program and may in the future hedge selected significant transactions denominated in currencies other than the U.S. dollar if and/or as we expand our international operations and our risk grows.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K. An index of those financial statements is found in Index to the Consolidated Financial Statements of this Annual Report on Form 10-K, as incorporated by reference into Item 15, Exhibits and Financial Statement Schedules, of this Annual Report on Form 10-K.

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

None.

Item 9A. Controls and Procedures.

We have established disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) designed to ensure that information required to be disclosed 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 and is accumulated and communicated to management, including the principal executive officer (our Chief Executive Officer) and principal financial officer (our Chief Financial Officer), to allow timely decisions regarding required disclosure. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management has evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report on Form 10-K. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures have been designed to provide reasonable assurance of achieving their objectives. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2025, our disclosure controls and procedures were effective.

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. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, a company's principal executive officer and principal financial officer, or persons performing similar functions, and effected by a company's board of directors, management, and other personnel, 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 and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of a company's assets;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that a company's receipts and expenditures are being made only in accordance with authorizations of the company's management and directors; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Our internal control over financial reporting is a process designed under the supervision of our principal executive officer and principal financial officer to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with U.S. generally accepted accounting principles.

Under the supervision of and with the participation of our principal executive officer and principal financial officer, our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2025 based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework (2013 framework). Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2025.

Our independent registered public accounting firm has issued an attestation report of our internal control over financial reporting. This report appears below.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended December 31, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Relay Therapeutics, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Relay Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2025, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Relay Therapeutics, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2025, and the related notes and our report dated February 26, 2026 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the 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 risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 26, 2026

Item 9B. Other Information.

Rule 10b5-1 Trading Plans

The following table describes, for the three month period ended December 31, 2025, each trading arrangement for the sale or purchase of our securities adopted, materially modified, or terminated by our directors and officers that is a contract, instruction, or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act, or a Rule 10b5-1 trading arrangement. No other officers or directors adopted, materially modified, or terminated a Rule 10b5-1 trading arrangement or any non-Rule 10b5-1 trading arrangement during the three month period ended December 31, 2025.

Name (Title)	Action Taken (Date of Action)	Type of Trading Arrangement	Expiration Date	Aggregate Number of Securities
Donald A. Bergstrom (President, Research and Development)	Adoption (10/30/2025)	Rule 10b5-1 Trading Arrangement	The earlier of (i) 11/20/2026 and (ii) the completed sale of the maximum shares subject to the plan.	Up to 120,915 Shares
Peter Rahmer (Chief Corporate Development Officer)	Adoption (10/31/2025)	Rule 10b5-1 Trading Arrangement	The earlier of (i) 10/15/2026 and (ii) the completed sale of the maximum shares subject to the plan.	Up to 100,000 Shares
Thomas Catinazzo (Chief Financial Officer)	Adoption (10/30/2025)	Rule 10b5-1 Trading Arrangement	The earlier of (i) 12/17/2026 and (ii) the completed sale of the maximum shares subject to the plan.	Up to 388,418 Shares
Sanjiv K. Patel (President and Chief Executive Officer)	Adoption (10/30/2025)	Rule 10b5-1 Trading Arrangement	The earlier of (i) 11/23/2026 and (ii) the completed sale of the maximum shares subject to the plan.	Up to 240,998 Shares

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 and Exchange Commission, or SEC, with respect to our 2026 Annual Meeting of Stockholders within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K 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 (excluding the information under the subheading "Pay Versus Performance") to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K 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 SEC with respect to our 2026 Annual Meeting of Stockholders within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K 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 SEC with respect to our 2026 Annual Meeting of Stockholders within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

Our independent public accounting firm is Ernst & Young LLP, Boston, Massachusetts, United States, PCAOB Auditor ID 42.

The information required by this Item 14 will be set forth in the section headed " – Ratification of the Appointment of Ernst & Young LLP as Relay Therapeutics' Independent Registered Public Accounting Firm for the Fiscal Year Ending December 31, 2026" in our Definitive Proxy Statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(1) For a list of the financial statements included herein, see Index to the Consolidated Financial Statements 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) The exhibits filed as part of this Annual Report on Form 10-K are set forth on the Exhibit Index immediately preceding the signature page of this Annual Report on Form 10-K. The Exhibit Index is incorporated herein by reference.

Item 16. Form 10-K Summary

Not applicable.

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Relay Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Relay Therapeutics, Inc. (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2025, and the related notes (collectively referred to as the "consolidated financial statements").

In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2025, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 26, 2026 expressed an unqualified opinion thereon.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Prepaid and Accrued Research and Development Expenses

Description of the Matter

As of December 31, 2025, the Company has recognized prepaid expenses of $17.8 million, which includes prepaid research and development expenses, and accrued external research and development costs of $12.6 million. As discussed in Note 2 to the consolidated financial statements, the Company makes estimates of prepaid and accrued research and development expenses at each balance sheet date by analyzing the progress of the services, including the phase or completion of events, invoices received and contracted costs from external third parties.

Auditing the Company's estimates of prepaid and accrued external research and development expenses related to contract research organizations in connection with clinical trials, which are included within the prepaid and accrued research and development expenses, is challenging and judgmental, as the amounts are based on various estimates from third-party vendors, as well as other inputs estimated by members of management, such as, the time period over which services will be performed, enrollment of patients, number of sites activated, and the level of effort expended during the reporting period. Additionally, due to the duration of the Company's research and development activities and the timing of invoicing received from third parties, the actual amounts incurred are not typically known by the date the financial statements are issued.

How We Addressed the Matter in Our Audit	We obtained an understanding, evaluated the design and tested the operating effectiveness of internal controls related to the Company's process for recording prepaid and accrued research and development expenses, including controls over management's review of the assumptions described below. To test prepaid and accrued research and development expenses related to contract research organizations, our audit procedures included, among others, testing the completeness and accuracy of the underlying data used in the Company's calculations and evaluating the significant assumptions used, as described above, by management to estimate the recorded prepaid and accrued research and development expenses. To assess the reasonableness of the significant assumptions, we corroborated the progress of clinical trials by inquiring of the Company's clinical team responsible for overseeing its clinical trial activities, obtained and verified information directly from third parties related to patient enrollment, number of active sites, billings, and costs of services, and performed a sensitivity analysis to assess the impact of reasonable changes in assumptions. In addition, we compared the costs for a sample of transactions against the related invoices and contracts and examined a sample of subsequent payments, invoices, and confirmations from the contract research organization to evaluate the accuracy of research and development expense and compared the results to the prepaid and accrued balances at December 31, 2025.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2017.

Boston, Massachusetts

February 26, 2026

Relay Therapeutics, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 84,018	$ 124,287
Investments	470,500	657,036
Prepaid expenses	17,787	17,348
Other current assets	5,974	10,533
Total current assets	578,279	809,204
Property and equipment, net	1,726	5,911
Operating lease assets	39,990	51,762
Restricted cash	1,336	2,119
Intangible asset	—	2,300
Total assets	$ 621,331	$ 871,296
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 7,705	$ 14,097
Accrued expenses	13,645	21,236
Operating lease liabilities	3,765	5,727
Deferred revenue	—	7,679
Other current liabilities	463	1,990
Total current liabilities	25,578	50,729
Operating lease liabilities, net of current portion	28,693	42,775
Total liabilities	54,271	93,504
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Undesignated preferred stock, $0.001 par value, 10,000,000 shares authorized as of December 31, 2025 and December 31, 2024; no shares issued and outstanding as of December 31, 2025 and December 31, 2024	—	—
Common stock, $0.001 par value; 300,000,000 shares authorized as of December 31, 2024 and December 31, 2024; 173,868,949 and 167,755,715 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively	168	168
Additional paid-in capital	2,580,928	2,516,905
Accumulated other comprehensive loss	733	(991)
Accumulated deficit	(2,014,769)	(1,738,290)
Total stockholders' equity	567,060	777,792
Total liabilities and stockholders' equity	$ 621,331	$ 871,296

See accompanying notes.

Relay Therapeutics, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)

	Year Ended December 31,		
	2025	2024	2023
Revenue:			
License and other revenue	$ 15,355	$ 10,007	$ 25,546
Total revenue	15,355	10,007	25,546
Operating expenses:			
Research and development expenses	$ 261,383	$ 319,089	$ 330,018
Change in fair value of contingent consideration liability	—	(13,206)	(6,422)
General and administrative expenses	56,710	76,592	74,950
Total operating expenses	318,093	382,475	398,546
Loss from operations	(302,738)	(372,468)	(373,000)
Other income:			
Interest income	27,035	34,746	31,045
Other (expense) income	(776)	14	(18)
Total other income, net	26,259	34,760	31,027
Net loss	$ (276,479)	$ (337,708)	$ (341,973)
Net loss per share, basic and diluted	$ (1.61)	$ (2.36)	$ (2.79)
Weighted average shares of common stock, basic and diluted	171,586,558	142,867,844	122,576,527
Other comprehensive income (loss):			
Unrealized holding gain (loss)	1,724	(795)	10,224
Total other comprehensive income (loss)	1,724	(795)	10,224
Total comprehensive loss	$ (274,755)	$ (338,503)	$ (331,749)

See accompanying notes.

Relay Therapeutics, Inc.
Consolidated Statements of Stockholders' Equity
(In thousands, except share and per share data)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive Income/(Loss)	Accumulated	Total Stockholders'
	Shares	Par Value	Capital		Deficit	Equity
Balances at December 31, 2022	121,112,234	$ 121	$ 2,019,126	$ (10,420)	$ (1,058,609)	$ 950,218
Issuance of common stock upon milestone achievement	1,797,064	2	12,748	—	—	12,750
Issuance of common stock via at-the-market offerings, net	3,026,072	3	30,278	—	—	30,281
Issuance of common stock through exercise of stock options	399,498	1	1,985	—	—	1,986
Issuance of common stock via employee stock purchase plan	244,125	—	2,486	—	—	2,486
Vesting of restricted stock units	883,416	—	—	—	—	—
Stock compensation expense	—	—	86,031	—	—	86,031
Unrealized gain on investments	—	—	—	10,224	—	10,224
Net loss	—	—	—	—	(341,973)	(341,973)
Balance at December 31, 2023	127,462,409	$ 127	$ 2,152,654	$ (196)	$ (1,400,582)	$ 752,003
Issuance of common stock through Private Placement, net	2,500,000	3	29,800	—	—	29,803
Issuance of common stock via at-the-market offerings, net	1,889,597	2	17,930	—	—	17,932
Issuance of common stock through follow-on offering, net	32,857,143	33	218,124	—	—	218,157
Issuance of common stock through exercise of stock options	617,570	2	2,780	—	—	2,782
Issuance of common stock via employee stock purchase plan	303,670	1	1,478	—	—	1,479
Vesting of restricted stock units	2,125,326	—	—	—	—	—
Stock compensation expense	—	—	94,139	—	—	94,139
Unrealized loss on investments	—	—	—	(795)	—	(795)
Net loss	—	—	—	—	(337,708)	(337,708)
Balances at December 31, 2024	167,755,715	$ 168	$ 2,516,905	$ (991)	$ (1,738,290)	$ 777,792
Issuance of common stock through exercise of stock options	111,209	—	524	—	—	524
Issuance of common stock via employee stock purchase plan	364,846	—	1,080	—	—	1,080
Vesting of restricted stock units	5,637,179	—	—	—	—	—
Stock compensation expense	—	—	62,419	—	—	62,419
Unrealized gain on investments	—	—	—	1,724	—	1,724
Net loss	—	—	—	—	(276,479)	(276,479)
Balances at December 31, 2025	173,868,949	$ 168	$ 2,580,928	$ 733	$ (2,014,769)	$ 567,060

See accompanying notes.

Relay Therapeutics, Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2025	2024	2023
Cash flows from operating activities:			
Net loss	$ (276,479)	$ (337,708)	$ (341,973)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation expense	3,557	5,464	5,269
Stock compensation expense	62,419	94,139	86,031
Impairment of intangible asset	2,300	—	—
Net realized gain on sale of investments	—	(101)	—
Loss on disposal of property and equipment	1,003	—	—
Change in fair value of contingent consideration liability	—	(13,206)	(6,422)
Net amortization of premiums and discounts on investments	(4,949)	(12,315)	(10,763)
Changes in assets and liabilities:			
Accounts receivable	—	—	306
Contract asset	—	—	4,913
Prepaid expenses and other current assets	1,612	(5,356)	(4,648)
Operating lease assets and liabilities, net	(4,272)	1,243	1,509
Accounts payable and accrued expenses	(11,440)	10,268	(9,590)
Deferred revenue	(7,679)	7,679	—
Other liabilities	(1,527)	786	(24,948)
Net cash used in operating activities	(235,455)	(249,107)	(300,316)
Cash flows from investing activities:			
Purchases of property and equipment	(410)	(2,018)	(4,126)
Purchases of investments	(122,971)	(650,629)	(385,542)
Proceeds from maturities and sales of investments	316,180	611,564	647,302
Net cash provided by (used in) investing activities	192,799	(41,083)	257,634
Cash flows from financing activities:			
Proceeds from issuance of common stock through Private Placement, net	—	29,803	—
Proceeds from issuance of common stock via at-the-market offerings, net	—	17,932	30,281
Proceeds from issuance of common stock through follow-on offering, net	—	218,157	—
Proceeds from issuance of common stock through exercise of stock options	524	2,782	1,986
Proceeds from issuance of common stock via employee stock purchase plan	1,080	1,479	2,486
Net cash provided by financing activities	1,604	270,153	34,753
Net decrease in cash, cash equivalents, and restricted cash	(41,052)	(20,037)	(7,929)
Cash, cash equivalents, and restricted cash at beginning of period	126,406	146,443	154,372
Cash, cash equivalents, and restricted cash at end of period	$ 85,354	$ 126,406	$ 146,443
Supplemental disclosure of non-cash activities:			
Periodic change in additions of property and equipment within current liabilities	$ (35)	$ (1,544)	$ 410
Periodic change in costs to obtain license agreement within current liabilities	$ (2,508)	$ 2,508	$ —
Operating lease assets obtained in exchange for operating lease liabilities	$ 6,908	$ —	$ —
Issuance of common stock upon milestone achievement	$ —	$ —	$ 12,750

Reconciliation of Cash, Cash Equivalents, and Restricted Cash from Balance Sheets to Statements of Cash Flows

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Cash and cash equivalents	$ 84,018	$ 124,287
Restricted cash	1,336	2,119
Cash, cash equivalents, and restricted cash per statements of cash flows	$ 85,354	$ 126,406

See accompanying notes.

1. Nature of Business and Basis of Presentation

Relay Therapeutics, Inc. (the "Company") was incorporated in Delaware on May 4, 2015 and is headquartered in Cambridge, Massachusetts. The Company is a clinical-stage, small molecule precision medicine company developing potentially life-changing therapies for patients living with cancer and genetic disease. The Company's Dynamo® platform integrates an array of leading-edge computational and experimental approaches designed to drug protein targets that have previously been intractable or inadequately addressed. The Company's initial focus is on enhancing small molecule therapeutic discovery in targeted oncology and genetic disease indications. The Company's lead product candidate, zovegalisib (RLY-2608), is in clinical development. The Company is also progressing its NRAS-selective inhibitor, RLY-8161, to address NRAS-mutated solid tumors, as well as its non-inhibitory chaperone for Fabry disease. The Company is also advancing early-stage discovery programs across both precision oncology and genetic diseases.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations, and the need to obtain additional financing. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure, and extensive compliance-reporting capabilities.

The Company's product candidates are in development. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval, or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants.

The Company has devoted substantially all of its resources to developing its product candidates by integrating its computational and experimental approaches, building its intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations.

The Company has incurred net operating losses since inception and had an accumulated deficit of $2.0 billion as of December 31, 2025. The Company expects that its existing cash, cash equivalents, and investments as of December 31, 2025 will enable it to fund its planned operating expenses and capital expenditures for at least one year from the date of the issuance of these consolidated financial statements. The future viability of the Company is dependent on its ability to generate cash from operating activities or to raise additional capital to finance its operations. The Company's failure to raise capital as and when needed could have a material adverse effect on its financial condition and ability to pursue its business strategies. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into license or collaboration arrangements or obtain government grants. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. If the Company is unable to obtain funding, the Company could be forced to delay, reduce, or eliminate its research and development programs, product portfolio expansion, or commercialization efforts, which could adversely affect its business prospects. In the event the Company requires additional funding, there can be no assurance that it will be successful in obtaining sufficient funding on terms acceptable to the Company to fund its continuing operations, if at all.

2. Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") and pursuant to the rules and regulations of the U.S. Securities and Exchange Commission ("SEC") for reporting on Form 10-K.

The Company's consolidated financial statements include the accounts of Relay Therapeutics, Inc. and its wholly-owned subsidiaries, Relay Therapeutics Securities Corporation and Relay ML Discovery, LLC.

All intercompany balances and transactions have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these

consolidated financial statements include, but are not limited to, the fair value of contingent milestone payments in connection with the acquisition of ZebiAI Therapeutics, Inc. ("ZebiAI") in 2021, the determination of the transaction price and standalone selling price of performance obligations under Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers ("ASC 606"), the timing of expense recognition for certain research and development activities, the valuation of equity instruments, and the incremental borrowing rate for determining operating lease assets and liabilities. Estimates are periodically reviewed in light of changes in circumstances, facts, and experience.

Segments

In general, segments are identified as components of an enterprise or business about which separate discrete financial information is available for evaluation by the chief operating decision maker ("CODM") in making decisions on how to allocate resources and assess performance of the enterprise or business.

In November 2023, the FASB issued Accounting Standards Update ("ASU") 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures ("ASU 2023-07"), which is intended to provide enhancements to segment disclosures, even for entities with one reportable segment. In particular, the standard requires disclosure of significant segment expenses regularly (a) provided to the CODM and (b) included within each reported measure of segment profit and loss. The standard also requires disclosure of all other segment items by reportable segment and a description of its composition. Finally, the standard requires disclosure of the title and position of the CODM and an explanation of CODM uses the reported measure(s) of segment profit or loss in assessing segment performance and deciding how to allocate resources.

The Company adopted ASU 2023-07 upon filing its Annual Report on Form 10-K for the year ended December 31, 2024.

The Company's CODM is the President and Chief Executive Officer.

The Company and the CODM view the Company's operations as one segment, which is using innovative experimental and computational approaches on protein motion for making medicines to drug protein targets that have previously been intractable or inadequately addressed.

For further considerations, refer to Note 3, *Segment Information*.

Cash Equivalents

The Company considers all short-term, highly liquid investments with original maturities of 90 days or less at acquisition date to be cash equivalents. Cash equivalents, which consist of money market funds, are stated at fair value.

Restricted Cash

As of December 31, 2025 and 2024, the Company had restricted cash of $1.3 million and $2.1 million, respectively, to secure letters of credit in connection with the Company's operating leases, as detailed in Note 12, *Operating Leases*. The Company classified the restricted cash as a noncurrent asset on its consolidated balance sheets, consistent with the terms of the operating lease agreements.

Investments

Investments in marketable securities are classified as available-for-sale.

Investments are measured and reported at fair value using quoted prices in active markets for similar securities.

Premiums or discounts from par value are amortized to interest income over the life of the underlying investment.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"). Certain amendments thereto were also issued by the FASB. The Company adopted ASU 2016-13, as well as the related amendments thereto, on January 1, 2022, pursuant to which the Company reviews investments whenever the fair value of an investment is less than the amortized cost and evidence indicates that an investment’s carrying amount is not recoverable within a reasonable period of time. In connection therewith, the Company evaluates whether the decline in fair value has resulted from credit losses or other factors, considering the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency, and adverse conditions specifically related to the security, among other factors. If the assessment indicates a credit loss exists, the present value of cash flows expected to be collected from the security is compared to the amortized cost basis of the security. If the present value of cash flows expected to be collected is less than the amortized cost basis, a credit loss exists and an allowance for credit losses is recorded on the consolidated balance sheet, limited by the amount that the fair value is less than the amortized cost basis. Any impairment not related to credit is recognized in other comprehensive loss as a separate component of stockholders' equity. Changes in the allowance for credit losses are recorded as a provision for (or reversal of) credit loss expense in general and administrative expenses within the consolidated statements of operations and comprehensive loss. Losses are charged against the allowance when the Company believes the uncollectability of an available-for-sale security is confirmed or when either of the criteria regarding intent or requirement to sell is met.

In the event no credit losses are identified, the entire change in fair value of investments are recognized as unrealized gains and losses, which are included as a component of accumulated other income/(loss) on the consolidated balance sheets and statements of stockholders' equity, as well as a component of other comprehensive income/(loss) on the consolidated statements of operations and comprehensive loss, until realized. To the extent there are realized gains/(losses), such amounts are specifically identified and included in interest income.

All of the Company's available-for-sale securities are available to the Company for use in current operations. As a result, the Company classified all such securities as current assets as of December 31, 2025 and 2024, although the stated maturity of some individual securities may be one year or more beyond the balance sheet dates.

Concentration of Credit Risk and Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents, and investments. From time to time, the Company has maintained all of its cash, cash equivalents, and investments at certain accredited financial institutions in amounts that exceed federally insured limits. The Company generally invests its excess capital in money market funds, U.S. treasury bonds, U.S. treasury bills, and agency bonds, all of which are subject to minimal credit and market risk. Management has established guidelines relative to credit ratings and maturities intended to safeguard principal balances and maintain liquidity. The investment portfolio is maintained in accordance with the Company's investment policy, which defines allowable investments, specifies credit quality standards, and limits the credit exposure of any single issuer.

The Company is dependent on third-party suppliers for research and development activities of its programs, including preclinical and clinical testing. In particular, the Company relies and expects to continue to rely on a small number of these suppliers, as discussed in Note 11, *Commitments and Contingencies*, to meet its requirements for certain of its programs. These programs could be adversely affected by a significant interruption in preclinical and clinical testing, as well as the supply of active pharmaceutical ingredients and formulated drugs.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP.

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable.

- Level 1—Quoted prices in active markets for identical assets or liabilities.

- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies, and similar techniques.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation is recognized using the straight-line method over the useful life of the asset. Laboratory and computer equipment are depreciated over three years. Furniture and fixtures are depreciated over five years. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the asset. Expenditures for repairs and maintenance of assets are charged to expense as incurred. Upon retirement or sale, the cost and related accumulated depreciation of assets disposed of are removed from the accounts and any resulting gain or loss is included in loss from operations.

Property and equipment, net consisted of the following:

	December 31,	
	2025	2024
	(in thousands)	
Property and equipment:		
Laboratory equipment	$ 20,586	$ 27,407
Leasehold improvements	908	3,825
Computer equipment	986	1,743
Furniture and fixtures	793	1,779
Construction in process	—	69
	23,273	34,823
Less: accumulated depreciation	(21,547)	(28,912)
Total property and equipment, net	$ 1,726	$ 5,911

Impairment of Long-Lived Assets

The Company continually evaluates long-lived assets for potential impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparing the book values of the assets to the expected future net undiscounted cash flows the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured in an amount by which the book values of the assets exceed their fair value.

The Company did not recognize any impairment losses for the years ended December 31, 2024 and 2023.

In connection with the acquisition of ZebiAI in 2021, the Company recorded an intangible asset for the assembled workforce of $2.3 million. During the year ended December 31, 2025, over 70 employees were involuntarily terminated, after which the Company concluded there was no ongoing benefit from the assembled workforce. Therefore, the intangible asset was considered to be impaired and written-off within research and development expenses during the year ended December 31, 2025.

The Company did not recognize any other impairment losses for the year ended December 31, 2025.

Research and Development Costs

In general, research and development expenses include salaries, stock compensation and benefits of employees, third-party license fees, and other operational costs incurred in connection with the Company’s research and development activities, including allocated facility expenses and external costs of outside vendors engaged to conduct both preclinical studies and clinical trials. Nonrefundable 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.

The Company expenses research and development costs as incurred. When evaluating the adequacy of expense recognized, particularly from services performed by external third parties, the Company analyzes progress of the services, including the phase or completion of events, invoices received, and contracted costs. Judgments and estimates are made in determining the expense recognized and the related prepaid or accrued balances at the end of any reporting period. Actual results could differ from the Company’s estimates. The Company’s historical estimates have not been materially different from the actual costs.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Stock Compensation

For stock options and restricted stock units ("RSUs") granted to employees, directors, and other consultants with vesting over specified periods of continued service, the Company measures their fair value on the grant date using (a) the Black-Scholes Option Pricing Model for stock options and (b) the Company’s closing stock price on such date for RSUs. In connection therewith, compensation expense for such awards is recognized under the straight-line method over the requisite service period, which is generally the vesting period. The Company recognizes the impact of forfeitures on compensation expense as they occur.

For stock options and RSUs granted to employees, directors, and other consultants with vesting over specified periods of continued service and contingent upon achievement of certain performance conditions, the Company measures their fair value on the grant date using (a) the Black-Scholes Option Pricing Model for stock options and (b) the Company’s closing stock price on such date for RSUs. In connection

therewith, compensation expense for such awards is recognized under the accelerated attribution method over the requisite service period, which is generally the vesting period. The Company recognizes the impact of forfeitures on compensation expense as they occur.

For stock options and RSUs granted to employees, directors, and other consultants with vesting over specified periods of continued service and contingent upon achievement of certain market conditions, the Company measures their fair value on the grant date using a Monte Carlo Simulation, incorporating various option pricing inputs. In connection therewith, compensation expense for such awards is recognized under the accelerated attribution method over the derived service period or requisite service period, whichever is longer, regardless of whether the market conditions have been achieved. The Company recognizes the impact of forfeitures on compensation expense as they occur.

Revenue Recognition

The Company accounts for revenue recognition in accordance with ASC 606, pursuant to which an entity recognizes revenue when its customer obtains control of promised goods or services in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps at contract inception: (i) identify the contract(s) with customer(s); (ii) identify the performance obligation(s) in the contract(s); (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract(s); and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

Once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within the contract and determines those that are performance obligations at contract inception. The Company then determines the transaction price and allocates it to the performance obligations. As part of the accounting for such arrangements, the Company must use judgment to determine: (a) the number of performance obligations based on the determination under step (ii) above; (b) the transaction price under step (iii) above, including the determination of whether milestones or other variable consideration should be included in the transaction price; and (c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of the transaction price in step (iv) above.

The Company utilizes key assumptions and judgments in (a) determining the stand-alone selling price for each performance obligation, which may include discounted cash flow models, evaluation of comparable transactions, and pricing considered in negotiating the transaction and estimated costs, and (b) determining how the transaction price is allocated amongst the performance obligations. The Company also uses judgment to determine whether milestones or other variable consideration should be included in the transaction price. As part of management’s evaluation of the transaction price, the Company considers numerous factors, including whether the achievement of the milestones is outside of the Company's control, contingent upon the efforts of others, or subject to scientific risks of success. If the Company concludes it is probable that a significant revenue reversal would not occur, the associated milestone payment is included in the transaction price. Milestone payments that are not within the Company's control, such as regulatory approvals, are generally not considered probable until those milestones are achieved. The Company re-evaluates the transaction price, including estimated variable consideration included in the transaction price and all constrained amounts, in each reporting period and as uncertain events are resolved or other changes in circumstances occur. For revenue-based royalties, including milestone payments based on the level of sales, the Company will include royalties in the transaction price at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty is allocated has been satisfied (or partially satisfied).

Once the performance obligations are identified, the transaction price is allocated to each performance obligation based on the relative stand-alone selling price. The Company then recognizes as revenue the amount of the transaction price allocated to the respective performance obligation when (or as) it is satisfied, either at a point in time or over time. If the performance obligation is satisfied over time, the Company recognizes revenue based on the use of either an output or input method.

Contract Assets and Liabilities

In general, a contract asset is an entity's right to consideration in exchange for goods or services the entity has transferred to a customer when the right is conditioned on something besides the passage of time. The Company recognizes a contract asset when it transfers goods or services to a customer before the customer pays consideration and/or before payment is due, excluding any amounts presented as a receivable. The Company also assesses contract assets for credit losses.

In general, a contract liability, or deferred revenue, primarily relates to amounts for which an entity has received payment or has the unconditional right to receive payment in the future, but has not yet satisfied the related performance obligations. The Company records such payments or consideration due as deferred revenue and until it satisfies the performance obligations under such arrangements. In connection therewith, upfront payments from the Company's licensing agreements do not represent financing, as the payment is not funding the transfer of good or services and the technology under the licenses granted reflects research and development expenses already incurred.

Leases

Pursuant to ASC Topic 842, Leases ("ASC 842"), the Company determines if an arrangement is or contains a lease at inception. For leases with a term of 12 months or less, the Company does not recognize a right-of-use asset or lease liability. The Company’s operating leases

are recognized on its consolidated balance sheets as other noncurrent assets, other current liabilities, and other noncurrent liabilities. The Company does not have any finance leases.

Right-of-use assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. As the Company's leases typically do not provide an implicit rate, the Company uses an estimate of its incremental borrowing rate based on the information available at lease commencement in determining the present value of lease payments. Operating lease right-of-use assets also include the effect of any lease payments made prior to commencement and exclude lease incentives. The lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense is recognized on a straight-line basis over the lease term.

The Company has lease agreements with lease and non-lease components, which are accounted for as a combined element.

Comprehensive Loss

Comprehensive loss includes net loss, as well as other changes in stockholders' equity resulting from transactions and economic events other than those with stockholders. For the years ended December 31, 2025, 2024, and 2023, other comprehensive income (loss) consisted of changes in unrealized gains and losses from available-for-sale investments.

Net Loss per Common Share

Basic net loss per share is computed using the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed using the sum of the weighted-average number of common shares outstanding during the period and the effect of any dilutive securities. For periods in which the Company reports a net loss, diluted net loss per share is the same as basic net loss per share, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

For additional discussion of net loss per common share, please refer to Note 9, *Net Loss per Share.*

Income Taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events recognized in the Company's financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on differences between the financial statement carrying amounts and the tax bases of the assets and liabilities using the enacted tax rates in effect in the years in which the differences are expected to reverse. A valuation allowance against deferred tax assets is recorded if, based on the weight of the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. The tax position first must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate. as well as the related net interest and penalties.

Recently Adopted Accounting Pronouncements

As noted above, the Company adopted (a) ASU 2016-13, as well as the related amendments thereto, on January 1, 2022 and (b) ASU 2023-07 upon filing of its Annual Report on Form 10-K for the year ended December 31, 2024. The adoption of the standards noted did not have a material impact on the Company's consolidated financial statements or footnotes, except as otherwise noted.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which is intended to provide enhancements to annual income tax disclosures. In particular, the standard requires more detailed information in the income tax rate reconciliation, as well as other enhancements. The standard is effective for years beginning after December 15, 2024 and early adoption was permitted. The Company adopted the standard upon filing of this Annual Report on Form 10-K and such standard did not have a material impact on the Company's consolidated financial statements or footnotes.

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40), the objective of which is to improve disclosures around an entity's expenses. In particular, the standard will require disclosure of additional information about specific expense categories in the notes to the financial statements on an annual and interim basis. ASU 2024-03 is effective for years beginning after December 15, 2026, as well as for interim periods beginning after

December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact of the standard on the presentation of its condensed consolidated financial statements and footnotes.

3. Segment Information

As summarized in Note 2, *Significant Accounting Policies*, the Company's CODM is the President and Chief Executive Officer and the Company views its operations as one segment, which is using innovative experimental and computational approaches on protein motion for making medicines to drug protein targets that have previously been intractable or inadequately addressed. The factors used in determining the Company's segments include the nature of the Company's operating activities, the organizational and reporting structure, and the type of information provided to and reviewed by the Company's CODM to allocate resources and evaluate financial performance.

The measure of segment assets is reported on the Company's consolidated balance sheets as total consolidated assets. The Company only operates in the United States and all tangible assets, consisting of property and equipment and operating lease right-of-use assets, are held in the United States.

The Company's CODM uses consolidated net loss to evaluate the Company's expenditures and monitor budget-to-actual results. In connection therewith, the review of budget-to-actual results is used in assessing performance of the Company's one operating segment, as well as in establishing resource allocations across the Company.

The following tables illustrates information about segment revenue, significant segment expenses, and segment net loss.

	Year Ended December 31,		
	2025	2024	2023
		(in thousands)	
License and other revenue	$ 15,355	$ 10,007	$ 25,546
Less:			
Research and development expenses			
External costs for programs in clinical trials	$ 104,268	$ 92,096	$ 101,055
External costs for platform technologies and preclinical programs	38,526	76,392	76,471
Employee related expenses (1)	57,600	71,979	77,120
Other expenses (2)	19,930	22,302	22,512
General and administrative expenses (3)	31,793	33,309	36,510
Other segment expenses (income)			
Depreciation expense	3,557	5,464	5,269
Stock compensation expense in research and development expenses	37,981	51,622	48,351
Stock compensation expense in general and administrative expenses	24,438	42,517	37,680
Change in fair value of contingent consideration liability	—	(13,206)	(6,422)
Interest income	(27,035)	(34,746)	(31,045)
Other expense (income)	776	(14)	18
Segment net loss	(276,479)	(337,708)	(341,973)
Reconciliation to consolidated net loss:			
Adjustments or reconciling items	—	—	—
Consolidated net loss	$ (276,479)	$ (337,708)	$ (341,973)

The expense categories and amounts in the table above align with the segment-level information regularly provided to the CODM.

(1) "Employee related expenses" within research and development expenses excludes stock compensation expense.

(2) "Other expenses" within research and development expenses excludes depreciation expense.

(3) "General and administrative expenses" excludes stock compensation expense and depreciation expense.

4. Fair Value Measurements

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values:

	Fair Value Measurements as of December 31, 2025:			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets				
Cash equivalents:				
Money market funds	$ 80,313	$ —	$ —	$ 80,313
Total cash equivalents	80,313	—	—	80,313
Investments:				
U.S. treasury bills	—	401,184	—	401,184
U.S. agency securities	—	69,316	—	69,316
Total investments	—	470,500	—	470,500
Total assets	$ 80,313	$ 470,500	$ —	$ 550,813
Liabilities				
Contingent Milestone Payments	$ —	$ —	$ —	$ —
Total liabilities	$ —	$ —	$ —	$ —

	Fair Value Measurements as of December 31, 2024:			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets				
Cash equivalents:				
Money market funds	$ 122,128	$ —	$ —	$ 122,128
Total cash equivalents	122,128	—	—	122,128
Investments:				
U.S. treasury bills	—	564,083	—	564,083
U.S. agency securities	—	92,953	—	92,953
Total investments	—	657,036	—	657,036
Total assets	$ 122,128	$ 657,036	$ —	$ 779,164
Liabilities				
Contingent Milestone Payments	$ —	$ —	$ —	$ —
Total liabilities	$ —	$ —	$ —	$ —

In determining the fair value of its investments at each date presented above, the Company relied on quoted prices for similar securities in active markets or using other inputs that are observable or can be corroborated by observable market data.

Fair Value of Contingent Consideration

In 2021, the Company acquired ZebiAI.

Pursuant to the terms of the acquisition, the Company is liable for certain contingent consideration, including (a) up to $85.0 million in platform and program milestones ("Contingent Milestone Payments") and (b) up to $100.0 million in earnout payments ("Contingent Earnout Payments"), both payable to ZebiAI's former equity holders upon achievement.

The Company classified the Contingent Milestone Payments within Level 3 of the fair value hierarchy. Pursuant to ASC Topic 480, Distinguishing Liabilities from Equity ("ASC 480"), the Company has accounted for the Contingent Milestone Payments as a liability and remeasured the fair value at each reporting period based on the probability of achieving the milestones and timing. Significant judgment has been used in determining the underlying assumptions. In connection therewith, the liability was recorded at $0 on the consolidated balance sheet as of December 31, 2025.

The Company has not accounted for the Contingent Earnout Payments as derivatives under ASC Topic 815, Derivatives and Hedging ("ASC 815"). As such, they were only measured at fair value as of the acquisition date and have not been re-assessed at fair value as of each reporting period end. During the year ended December 31, 2024, the contingency was resolved without the consideration becoming payable. Therefore, the liability was recorded at $0 on the consolidated balance sheet as of December 31, 2025.

The following table reconciles the change in the contingent consideration liability:

	Year Ended December 31,		
	2025	2024	2023
	(in thousands)		
Balance at beginning of period	$ —	$ 13,206	$ 32,378
Change in fair value of Contingent Milestone Payments	—	(8,206)	(6,422)
Change in carrying value of Contingent Earnout Payments	—	(5,000)	—
Common stock issued upon milestone achievement	—	—	(12,750)
	$ —	$ —	$ 13,206

5. Investments

The fair value of available-for-sale investments by type of security was as follows:

	December 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
Investments:				
U.S. treasury bills	$ 357,852	$ 513	$ (2)	$ 358,363
U.S. agency securities	49,430	48	(2)	49,476
Total investments with a maturity of one year or less	407,282	561	(4)	407,839
U.S. treasury bills	42,670	151	—	42,821
U.S. agency securities	19,815	27	(2)	19,840
Total investments with a maturity of one to two years	62,485	178	(2)	62,661
Total investments	$ 469,767	$ 739	$ (6)	$ 470,500

	December 31, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
Investments:				
U.S. treasury bills	$ 245,208	$ 516	$ (35)	$ 245,689
U.S. agency securities	51,153	123	—	51,276
Total investments with a maturity of one year or less	296,361	639	(35)	296,965
U.S. treasury bills	319,625	376	(1,607)	318,394
U.S. agency securities	42,041	14	(378)	41,677
Total investments with a maturity of one to two years	361,666	390	(1,985)	360,071
Total investments	$ 658,027	$ 1,029	$ (2,020)	$ 657,036

The following tables summarize the Company's available-for-sale debt securities in an unrealized loss position for which an allowance for credit losses has not been recorded, aggregated by major security type and length of time in a continuous unrealized loss position:

	December 31, 2025					
	Less than 12 Months		12 Months or Longer		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
	(in thousands)					
U.S. treasury bills	$ 11,057	$ (1)	$ 4,012	$ (1)	$ 15,069	$ (2)
U.S. agency securities	28,187	(4)	—	—	28,187	(4)
Total	$ 39,244	$ (5)	$ 4,012	$ (1)	$ 43,256	$ (6)

	December 31, 2024					
	Less than 12 Months		12 Months or Longer		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
	(in thousands)					
U.S. treasury bills	$ 258,196	$ (1,642)	$ —	$ —	$ 258,196	$ (1,642)
U.S. agency securities	35,455	(378)	—	—	35,455	(378)
Total	$ 293,651	$ (2,020)	$ —	$ —	$ 293,651	$ (2,020)

As summarized in the tables immediately above, the Company held 8 and 58 debt securities that were in an unrealized loss position as of December 31, 2025 and 2024, respectively. The unrealized losses at December 31, 2025 and 2024 were attributable to changes in interest rates and the unrealized losses do not represent credit losses. The Company does not intend to sell such securities and it is not more likely than not that it will be required to sell them before recovery of their amortized cost basis.

6. Accrued Expenses

Accrued expenses consisted of the following:

	December 31,	
	2025	2024
	(in thousands)	
External research and development costs	$ 12,631	$ 19,565
Consulting and professional services	822	935
Compensation costs	—	106
Other	192	630
Total accrued expenses	$ 13,645	$ 21,236

7. Common Stock

Each share of common stock entitles the stockholder to one vote on all matters submitted to a vote of the Company’s stockholders. Common stockholders are entitled to receive dividends, as may be declared by the Company’s board of directors. As of December 31, 2025, no dividends had been declared.

At-the-Market Offerings

In August 2021, the Company entered into a sales agreement (the "2021 Sales Agreement") with Cowen and Company, LLC ("Cowen"), pursuant to which the Company could offer and sell shares of its common stock having aggregate gross proceeds of up to $300.0 million from time to time in "at-the-market" offerings through Cowen, as the Company’s sales agent.

As of December 31, 2022, no shares of common stock had been sold under the 2021 Sales Agreement.

During the year ended December 31, 2023, the Company sold 3,026,072 shares of common stock under the 2021 Sales Agreement at a weighted-average price of $10.26 per share. The Company received proceeds of $30.3 million therefrom, which were net of $0.8 million in commissions paid to Cowen and other offering expenses.

During the year ended December 31, 2024, the Company sold 1,889,597 shares of common stock under the 2021 Sales Agreement at a weighted-average price of $9.73 per share. The Company received $17.9 million in proceeds therefrom, which were net of $0.5 million in commissions paid to Cowen and other offering expenses.

In August 2024, the 2021 Sales Agreement was terminated by mutual agreement between the Company and Cowen. Separately, the Company entered into a new sales agreement (the "2024 Sales Agreement") with TD Securities (USA) LLC ("TD Securities"), pursuant to which the Company may offer and sell shares of its common stock having aggregate gross proceeds of up to $250.0 million from time to time in "at-the-market" offerings through TD Securities, as the Company’s sales agent.

As of December 31, 2025, there were no sales of common stock under the 2024 Sales Agreement.

Private Placement

In January 2024, the Company entered into a securities purchase agreement with Nextech Crossover I SCP for the private placement of 2,500,000 shares of common stock at $12.00 per share (the "Private Placement"). The Company received $29.8 million in proceeds from the Private Placement, which was net of $0.2 million in offering expenses.

Follow-On Offering

In September 2024, the Company completed a public offering of 32,857,143 shares of common stock at an offering price of $7.00 per share. The Company received proceeds of $218.2 million, which was net of $11.8 million in underwriting discounts and other expenses.

8. Stock Compensation

In 2016, the Company adopted the 2016 Stock Option and Grant Plan (the "2016 Stock Plan"). Subsequent to July 2020, no further awards have been granted under the 2016 Stock Plan and all equity-based awards have been and will continue to be granted under the 2020 Stock Option and Incentive Plan (the "2020 Stock Plan"). To the extent outstanding options granted under the 2016 Stock Plan are cancelled, forfeited, or otherwise terminated without being exercised and would otherwise have been returned to the share reserve under the 2016 Stock Plan, the number of shares underlying such awards will be available for future grant under the 2020 Stock Plan.

In 2020, the Company's stockholders approved the 2020 Stock Plan. All of the Company's employees, officers, directors, and consultants are eligible to be granted options, restricted stock units, and other stock-based awards under the terms of the 2020 Stock Plan, which originally provided for the issuance of up to 8,376,080 of stock-based awards. The 2020 Stock Plan is also subject to annual increases to be added on the first day of each fiscal year, commencing on January 1, 2021, equal to 5% of the number of outstanding shares on the immediately preceding December 31 or such lesser number of shares approved by the Company's board of directors or compensation committee of the board of directors. On January 1, 2025, the number of shares available for issuance under the 2020 Stock Plan was increased by 8,387,785 shares of common stock. There were 12,009,179 stock-based awards available for issuance at December 31, 2025 under the 2020 Stock Plan.

In 2020, the Company adopted an Employee Stock Purchase Plan ("ESPP") that permits eligible employees to enroll in six-month offering periods. Participants may purchase shares of the Company's common stock, through after-tax payroll deductions, at a price equal to 85% of the fair market value of the common stock on the first or last day of the applicable six-month offering period, whichever is lower. Purchase dates under the ESPP occur on or about June 30 and December 31 each year. The Company's stockholders originally authorized 1,092,532 shares for issuance pursuant to the ESPP, which is subject to annual increases to be added on the first day of each fiscal year, commencing on January 1, 2021, equal to the lesser of 2,185,064 shares of the Company's common stock, 1% of the number of outstanding shares on the immediately preceding December 31, or an amount determined by the Company's board of directors. On January 1, 2025, the number of shares available for issuance under the ESPP was increased by 1,677,557 shares of common stock. There were 6,157,661 shares available for issuance at December 31, 2025 under the ESPP.

In connection with all stock-based payments, total stock compensation expense recognized was as follows:

	Year Ended December 31,		
	2025	2024	2023
		(in thousands)	
Research and development expenses	$ 37,981	$ 51,622	$ 48,351
General and administrative expenses	24,438	42,517	37,680
	$ 62,419	$ 94,139	$ 86,031

Time-Based Stock Options

The Company has historically granted stock options to employees, directors, and consultants with vesting subject to continued service over time. Accordingly, stock compensation expense for such awards is recognized using a straight-line attribution model over the vesting term.

The following table summarizes activity for time-based stock options for the year ended December 31, 2025:

	Number of Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Term (in Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	11,598,344	$ 17.44	6.93	$ —
Granted	8,244,529	4.36		
Exercised	(101,093)	4.67		
Cancelled	(2,971,776)	14.45		
Outstanding at December 31, 2025	16,770,004	$ 11.62	7.32	$ 39,083
Vested at December 31, 2025	9,331,796	$ 15.84	6.05	$ 12,979
Unvested at December 31, 2025	7,438,208	$ 6.33	8.91	$ 26,104

The total intrinsic value of time-based stock options exercised was $0.3 million, $6.7 million, and $4.4 million for the years ended December 31, 2025, 2024, and 2023, respectively.

The fair value of each time-based stock option granted is estimated on the grant date using the Black-Scholes option pricing model, pursuant to which the weighted-average grant date fair values were $3.09, $4.87, and $12.83 during the years ended December 31, 2025, 2024, and 2023, respectively.

The following table summarizes the assumptions used in calculating the fair value of the time-based stock options granted:

	Year Ended December 31,		
	2025	2024	2023
Expected term (in years)	6.25	6.25	6.25
Risk-free interest rate	3.7% to 4.7%	3.5% to 4.7%	3.3% to 5.0%
Expected volatility	77.3% to 78.7%	75.8% to 78.9%	74.1% to 79.8%
Expected dividend yield	0.0%	0.0%	0.0%

The Company uses the simplified method to calculate the expected term, as it does not have sufficient historical exercise data as a public company to provide a reasonable basis upon which to estimate the expected term for time-based stock options granted. The expected term is applied to the group of time-based stock option grants as a whole, as the Company does not expect substantially different exercise or post-vesting termination behavior amongst the Company's employees, directors, and consultants. The risk-free interest rate is based on a U.S. treasury instrument, whose term is consistent with the expected term of the time-based stock options. The Company's assumption for volatility is based on historical volatility of (a) the Company's stock price on the Nasdaq Global Market and (b) a group of peer companies with similar characteristics to the Company and who have similar risk profiles and positions within the industry. The Company has not historically issued dividends and, therefore, estimates none in calculating the grant date fair value of time-based stock options.

As of December 31, 2025, the total unrecognized stock compensation related to unvested time-based stock options was $27.6 million, which the Company expects to recognize over a weighted-average period of approximately 1.27 years.

Performance-Based Stock Options

In prior years, the Company granted options to certain employees with vesting subject to achievement of certain performance conditions, as well as continued service over time. Specifically, commencement of vesting was contingent on achievement of various goals over specified periods, subject to approval by either the Company's Board of Directors or President and Chief Executive Officer.

For the performance-based stock options, the Company applied variable accounting until the performance criteria were determined to be achieved, at which time vesting commenced over contractual service periods. Furthermore, because (a) the awards were authorized prior to the accounting grant date pursuant to ASC Topic 718, Stock Compensation ("ASC 718"), (b) the recipients were providing service prior to the accounting grant date, and (c) there were performance conditions that, if not met by the accounting grant date, would have resulted in the forfeiture of the award, the service inception dates preceded the accounting grant dates. Ultimately, the stock compensation expense for the options was determined based on the fair value of the awards on the accounting grant dates, which was then recognized using an accelerated attribution model over the vesting term commencing upon the actual or expected accounting grant dates.

For the performance-based stock options granted in prior years, all performance conditions were resolved in prior years and the grant dates were set prior to December 31, 2025.

The following table summarizes activity for performance-based stock options for the year ended December 31, 2025:

	Number of Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Term (in Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	1,556,684	$ 5.30	5.17	$ —
Exercised	(10,116)	5.22		
Cancelled	(69,175)	7.04		
Outstanding at December 31, 2025	1,477,393	$ 5.22	4.16	$ 4,787
Vested at December 31, 2025	1,477,393	$ 5.22	4.16	$ 4,787

The total intrinsic value of performance-based stock options exercised was $0.1 million, $0.1 million, and $0.3 million for the years ended December 31, 2025, 2024, and 2023, respectively.

The fair value of each performance-based stock option granted in prior years was estimated on the accounting grant date, or at the end of each reporting period if variable accounting was applied, using the Black-Scholes option-pricing model. There were no performance-based stock options granted during the years ended December 31, 2025, 2024, and 2023.

As of December 31, 2025, the total unrecognized stock compensation related to unvested performance-based stock options was $0.

Time-Based RSUs

The Company has historically granted RSUs to employees, directors, and consultants with vesting subject to continued service over time. Accordingly, stock compensation expense for such awards is recognized using a straight-line attribution model over the vesting term. The fair value of each time-based RSU is based on the closing price of the Company's common stock on the date of grant.

The following table summarizes activity for time-based RSUs for the year ended December 31, 2025:

	Number of Shares Underlying RSUs	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2024	5,808,659	$ 12.44
Granted	1,869,945	4.26
Vested	(4,269,481)	11.70
Cancelled	(992,105)	10.63
Unvested at December 31, 2025	2,417,018	$ 8.17

The fair value of time-based RSUs vested during the year ended December 31, 2025 was $18.1 million.

As of December 31, 2025, the total unrecognized compensation related to unvested time-based RSUs granted was $13.3 million, which the Company expects to recognize over a weighted-average period of approximately 1.03 years.

Performance-Based RSUs

Besides the 2023 Market-Based Awards, as defined below, the Company had only granted time-based RSUs to employees, directors, and consultants, as summarized above, prior to the year ended December 31, 2024. During the year ended December 31, 2024, the Company granted RSUs to certain employees with vesting subject to achievement of certain performance conditions, as well as continued service over time. Specifically, commencement of vesting was contingent on achievement of various goals over specified periods, subject to approval by either the Company's Board of Directors or Compensation Committee of the Board of Directors.

There were no other grants of similar awards during the year ended December 31, 2025.

For the performance-based RSUs, the Company applied variable accounting until the performance criteria were determined to be achieved, at which time vesting commenced over contractual service periods. Furthermore, because (a) the awards were authorized prior to the accounting grant date pursuant to ASC 718, (b) the recipients were providing service prior to the accounting grant date, and (c) there were performance conditions that, if not met by the accounting grant date, would have resulted in the forfeiture of the award, the service inception dates preceded the accounting grant dates. Ultimately, the stock compensation expense for the RSUs was determined based on the fair value of the awards on the accounting grant dates, which is then being recognized using an accelerated attribution model over the vesting term commencing upon the actual or expected accounting grant dates.

For the performance-based RSUs granted during the year ended December 31, 2024, the performance conditions were resolved during the year ended December 31, 2025 and, therefore, the accounting grant dates were set prior to December 31, 2025.

The following table summarizes activity for performance-based RSUs for the year ended December 31, 2025:

	Number of Shares Underlying RSUs	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2024	1,646,005	$ 4.09
Vested	(1,367,698)	4.11
Cancelled	(114,701)	3.80
Unvested at December 31, 2025	163,606	$ 4.19

The fair value of performance-based RSUs vested during the year ended December 31, 2025 was $5.7 million.

As of December 31, 2025, the total unrecognized compensation related to unvested performance-based RSUs granted was $0.1 million, which the Company expects to recognize during the three months ending March 31, 2026.

Market-Based Awards

During the year ended December 31, 2023, the Company granted 1,512,820 stock options and 405,770 RSUs to certain employees, with vesting over three years of continued service and contingent upon achievement of certain market conditions ("2023 Market-Based Awards"). The Company measured the fair value of the 2023 Market-Based Awards on the grant date using a Monte Carlo Simulation, incorporating various option pricing inputs. Ultimately, the fair value of the 2023 Market-Based Awards was estimated as $12.53 per share for the stock options and $16.11 per share for the RSUs, yielding a total of $25.5 million. The total compensation expense, or $25.5 million, is being recognized pursuant to the accelerated attribution method over the requisite service period of three years, regardless of whether the market conditions have been achieved. The impact of forfeitures, if any, will be recognized upon occurrence.

There were no other grants of similar awards during the years ended December 31, 2025 and 2024.

As of December 31, 2025, the market conditions underlying the 2023 Market-Based Awards had not been achieved and, therefore, none had vested. In connection therewith, none of the options were exercised and none of the RSUs were released through December 31, 2025. As of December 31, 2025, 211,420 options and 105,910 RSUs from the Market-Based Awards had been cancelled.

As of December 31, 2025, the total unrecognized compensation related to unvested market-based awards granted was $0.1 million, which the Company expects to recognize during the three months ending March 31, 2026.

Employee Stock Purchase Plan

The following table summarizes activity under the Company's ESPP during the years ended December 31, 2025, 2024, and 2023, including (a) after-tax contributions from employees, (b) shares purchased, and (c) weighted-average assumptions used in the Black-Scholes option pricing model to estimate the fair value of the option component of the shares purchased.

	Year Ended December 31,		
	2025	2024	2023
After-tax contributions (in thousands)	$ 1,080	$ 1,479	$ 2,486
Shares of common stock purchased	364,846	303,670	244,125
Expected term (in years)	0.50	0.50	0.50
Risk-free interest rate	4.3%	5.3%	5.1%
Expected volatility	87.0%	65.1%	86.8%
Expected dividend yield	0.0%	0.0%	0.0%

As of December 31, 2025, there was no unrecognized stock compensation expense related to ESPP, since the purchase for the offering period between July 1, 2025 and December 31, 2025 was transacted on December 31, 2025.

9. Net Loss per Share

The following table summarizes the computation of basic and diluted net loss per share of the Company:

	Year Ended December 31,		
	2025	2024	2023
	(in thousands, except share and per share data)		
Net loss	$ (276,479)	$ (337,708)	$ (341,973)
Net loss per share, basic and diluted	$ (1.61)	$ (2.36)	$ (2.79)
Weighted average shares of common stock, basic and diluted	171,586,558	142,867,844	122,576,527

For the years ended December 31, 2025, 2024, and 2023, the weighted-average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share is the same. In computing diluted net loss per share for the years ended December 31, 2025, 2024, and 2023, the Company excluded the following potentially dilutive securities, as the effect would be anti-dilutive and reduce the net loss per share calculated for each period.

	Year Ended December 31,		
	2025	2024	2023
Options outstanding to purchase common stock	19,548,797	14,570,218	15,610,586
Unvested and outstanding restricted stock units	2,880,484	7,811,619	3,398,017
Common stock issued upon milestone achievement	—	—	1,535,404
	22,429,281	22,381,837	20,544,007

The amounts included in the table above for options and RSUs are presented based on amounts outstanding at each period end.

The amounts included in the table above for common stock issued upon milestone achievement are presented based on the weighted-average anti-dilutive effect from shares issued in connection with Contingent Milestone Payments in each of the periods presented.

10. Collaboration and License Agreements

Genentech, Inc.

In December 2020, the Company and Genentech, Inc. ("Genentech") entered into the Collaboration and License Agreement (as amended from time to time, the "Genentech Agreement"), which granted Genentech a license to develop and commercialize migoprotafib (GDC-1971, formerly known as RLY-1971).

Effective as of January 7, 2025 (the "Termination Date"), Genentech elected to terminate the Genentech Agreement without cause. As a result of the termination of the Genentech Agreement, the Company is not entitled to receive any further milestones or other payments due after the Termination Date. The parties ceased to have any development or commercialization obligations after the Termination Date and the licenses the Company granted to Genentech pursuant to the Genentech Agreement ceased to be in effect as of the Termination Date.

Through the Termination Date, consideration under the Genentech Agreement totaled $121.8 million.

During the years ended December 31, 2025, 2024, and 2023, the Company recognized $0, $10.0 million, and $25.5 million, respectively, of revenue from the Genentech Agreement.

Elevar Therapeutics, Inc.

In December 2024, the Company and Elevar Therapeutics, Inc. ("Elevar") entered into the Exclusive License Agreement (as amended from time to time, the "Elevar Agreement"), pursuant to which Elevar was granted exclusive global development and commercialization rights for lirafugratinib (RLY-4008), the Company's selective oral small molecule inhibitor of fibroblast growth factor receptor 2 ("FGFR2"). Upon execution of the Elevar Agreement, Elevar is responsible for all further development activities and global commercialization for lirafugratinib in FGFR2-driven cholangiocarcinoma and FGFR2-altered other solid tumors.

As of December 31, 2025, consideration under the Elevar Agreement totaled $15.4 million, consisting of:

- $5.0 million upon execution;
- $3.4 million upon transfer of active pharmaceutical ingredient and other materials; and
- $7.0 million in milestone payments.

The Company is also eligible to receive up to $488.0 million in regulatory and commercial milestone payments, as well as tiered royalties.

Accounting Analysis

1. Identification of the Contract

The Company concluded Elevar was a customer and, as such, the Elevar Agreement was within the scope of ASC 606.

2. Identification of Performance Obligations

At commencement of the Elevar Agreement, the Company identified the following performance obligations:

- License to develop and commercialize lirafugratinib and the related know-how; and

- Transfer of active pharmaceutical ingredient and other materials related to lirafugratinib.

3. Determination of Transaction Price

As of December 31, 2025, the transaction price for the Elevar Agreement was $15.4 million, which included the payments noted above. In connection therewith, certain milestone payments and royalties were excluded from the transaction price as of December 31, 2025, because such payments were variable consideration fully constrained. As part of management's evaluation of the constraint, the Company considered numerous factors, including consideration of the fact that achievement of the milestones is outside of the Company's control, contingent upon Elevar's efforts, the receipt of regulatory approval, and subject to scientific risks of success.

4. Allocation of Transaction Price to Performance Obligations

The Company allocated the transaction price of $15.4 million to each performance obligation using estimates of their stand-alone selling prices ("SSP"). However, the estimates had no impact on the Company's consolidated financial statements through December 31, 2025, since each performance obligation was completed in the year ended December 31, 2025, as noted below.

5. Recognition of Revenue

During the year ended December 31, 2024, the Company recognized $0 in revenue from the Elevar Agreement, since none of the performance obligations thereunder were completed as of December 31, 2024.

During the year ended December 31, 2025, the Company recognized $15.4 million in revenue from the Elevar Agreement, specifically in connection with the completion of each of the Company's performance obligations thereunder in the current period, as well as receipt of certain milestone payments.

11. Commitments and Contingencies

Intellectual Property License

The Company has a Collaboration and License Agreement with D. E. Shaw Research, LLC ("D. E. Shaw Research"), pursuant to which the Company and D.E. Shaw Research jointly conducted research efforts with the goal of identifying and developing product candidates (as amended from time to time, the "DESRES Agreement"). The initial research term of the DESRES Agreement expired on August 16, 2025. The DESRES Agreement continues on a target-by-target basis until all payment obligations have expired.

The Company paid an annual collaboration fee of $9.9 million during the initial research term from 2021 to 2025. The Company is also obligated to pay development milestone payments under the terms of the DESRES Agreement up to $7.3 million per target, plus sales milestones and royalties, upon the achievement of certain specified contingent events. Such payments for achievement of development and regulatory milestones total up to $7.3 million in the aggregate for each of the first three products the Company develops and up to $6.3 million, in the aggregate, for each product the Company develops thereafter. The Company assessed the milestone events and royalties under the DESRES Agreement as of December 31, 2025 and 2024, concluding certain milestone payments were triggered as of December 31, 2025 and subsequently paid in January 2026 and no such payments were due as of December 31, 2024.

For the years ended December 31, 2025, 2024, and 2023, the Company recorded research and development expenses of $9.3 million, $9.7 million, and $9.5 million, respectively, under the DESRES Agreement on its consolidated statements of operations.

As of December 31, 2025 and 2024, the Company had prepaid balances of $0 and $5.9 million, respectively, under the DESRES Agreement on its consolidated balance sheets.

As of December 31, 2025 and 2024, the Company had accrued expense and accounts payable balances of $0.6 million and $0.1 million, respectively, under the DESRES Agreement on its consolidated balance sheets.

Other Research Arrangements

The Company has certain other research and license arrangements and other collaborations with third parties, which provide the Company with specified research and/or development services.

12. Operating Leases

399 Binney Street

In December 2017, the Company executed an operating lease agreement for 44,336 square feet of office and laboratory space at 399 Binney Street, Cambridge, Massachusetts, which was increased to 44,807 square feet in January 2018 ("399 Binney Street"). Pursuant to the terms of the operating lease agreement, as further amended in November 2019 and September 2020, the operating lease for 399 Binney Street was previously scheduled to expire on April 30, 2029.

On June 3, 2025, the Company and ARE MA Region No. 58 LLC ("399 Binney Street Landlord") executed another amendment to the operating lease for 399 Binney Street, as amended, pursuant to which termination was accelerated to July 3, 2025. The Company continued to be responsible for rent and other obligations under the operating lease for 399 Binney Street, as amended, through July 3, 2025, at which point such obligations ceased and the operating lease was terminated. In consideration for entry into the amendment on June 3, 2025, the Company also paid the 399 Binney Street Landlord a termination payment of $2.5 million (the "Termination Payment").

Although the Company was obligated to pay rent for the leased premises at 399 Binney Street through July 3, 2025 and the accelerated termination date was July 3, 2025, as agreed between Company and the 399 Binney Street Landlord, the Company had committed to terminating the operating lease for 399 Binney Street, as amended, as of June 3, 2025. Furthermore, the Company's access to the premises was also terminated as of June 3, 2025. Therefore, the Company accounted for termination of the operating lease at 399 Binney Street, as amended, during the three months ended June 30, 2025. In connection therewith, the Company removed the operating lease assets and liabilities from its consolidated balance sheet as of termination, or June 3, 2025, and also recognized the impact of the Termination Payment at such time.

The following table summarizes the adjustments above and reconciles to the net amount as of June 3, 2025:

	June 3, 2025
	(in thousands)
Assets:	
Operating lease assets	$ 13,190
Liabilities:	
Operating lease liabilities	$ (3,127)
Operating lease liabilities, net of current portion	(12,060)
Total operating lease liabilities	$ (15,187)
Other:	
Termination Payment	$ 2,452
Net:	
Carryover	$ 455

In the table above, the net amount of $0.5 million was recorded as an addition to the operating lease asset upon commencement of the operating lease for Building 300 at One Kendall Square, Cambridge, MA ("300 OKS"), as described below, during the year ended December 31, 2025. The amount is expected to be amortized as rent expense over the term of the operating lease at 300 OKS.

The following table summarizes the effect of lease costs for the operating lease at 399 Binney Street on the Company’s consolidated statements of operations for the years ended December 31, 2025, 2024, and 2023:

	Year Ended December 31,		
	2025	2024	2023
		(in thousands)	
Research and development expenses	$ 1,877	$ 3,648	$ 3,631
General and administrative expenses	307	595	614
	$ 2,184	$ 4,243	$ 4,245

The Company made cash payments of $2.2 million, $4.4 million, and $4.3 million under the operating lease agreement for 399 Binney Street during the years ended December 31, 2025, 2024, and 2023, respectively.

Building 300 at One Kendall Square

On June 3, 2025, the Company executed an operating lease agreement for 300 OKS with ARE MA Region No. 59 LLC ("300 OKS Landlord"), an affiliate of the 399 Binney Street Landlord. Pursuant to the terms of the operating lease agreement, the Company agreed to

lease 12,190 square feet of office space through February 28, 2030. In consideration for entry into the operating lease agreement, the Company also paid the 300 OKS Landlord a relocation payment of $3.5 million (the "Relocation Payment").

Although the Company was only obligated to start paying rent under the operating lease agreement at 300 OKS on July 3, 2025, the Company could physically access and benefit from the space upon lease execution on June 3, 2025. Therefore, the Company recorded an operating lease asset and liability during the three months ended June 30, 2025, which included $0.5 million from the net impact of terminating the lease at 399 Binney Street, as amended, on June 3, 2025. The operating lease agreement for 300 OKS expires in February 2030 with no renewal options.

The following table summarizes the presentation of amounts recorded on the Company's consolidated balance sheets for the operating lease at 300 OKS as of December 31, 2025 and 2024.

	December 31, 2025	December 31, 2024
	(in thousands)	
Assets:		
Operating lease assets	$ 6,513	$ —
Liabilities:		
Operating lease liabilities	$ 592	$ —
Operating lease liabilities, net of current portion	2,499	—
Total operating lease liabilities	$ 3,091	$ —

The following table summarizes the effect of lease costs for the operating lease at 300 OKS on the Company's consolidated statements of operations for the years ended December 31, 2025, 2024, and 2023:

	Year Ended December 31,		
	2025	2024	2023
		(in thousands)	
Research and development expenses	$ 881	$ —	$ —
General and administrative expenses	125	—	—
	$ 1,006	$ —	$ —

The Company made cash payments of $4.0 million, $0, and $0 under the operating lease agreement for 300 OKS during the years ended December 31, 2025, 2024, and 2023, respectively.

As of December 31, 2025, the minimum lease payments for the Company's operating lease at 300 OKS for the next five years and thereafter are expected to be as follows:

Year Ending December 31,	Amount (in thousands)
2026	$ 875
2027	899
2028	924
2029	949
2030	160
Thereafter	—
Total lease payments	3,807
Less: interest	(716)
Present value of operating lease liabilities	$ 3,091

The remaining lease term and discount rate of the Company's operating lease at 300 OKS were 4.16 years and 10.0%, respectively, at December 31, 2025.

60 Hampshire Street

In May 2021, the Company executed an operating lease agreement for 41,474 square feet of office and laboratory space at 60 Hampshire Street, Cambridge, Massachusetts ("60 Hampshire Street"). The Company gained control of the leased space in July 2022 and, accordingly, recorded an operating lease right-of-use asset and liability at such time. The operating lease expires in June 2032 with no renewal options.

The following table summarizes the presentation of amounts recorded on the Company's consolidated balance sheets for the operating lease at 60 Hampshire Street as of December 31, 2025 and 2024:

	December 31, 2025	December 31, 2024
	(in thousands)	
Assets:		
Operating lease assets	$ 33,477	$ 37,492
Liabilities:		
Current operating lease liabilities	$ 3,173	$ 2,784
Operating lease liabilities, net of current portion	26,194	29,367
Total operating lease liabilities	$ 29,367	$ 32,151

The following table summarizes the effect of lease costs for the operating lease at 60 Hampshire Street on the Company's consolidated statements of operations for the years ended December 31, 2025, 2024, and 2023:

	Year Ended December 31,		
	2025	2024	2023
		(in thousands)	
Research and development expenses	$ 5,776	$ 5,851	$ 5,549
General and administrative expenses	878	955	938
	$ 6,654	$ 6,806	$ 6,487

The Company made cash payments of $5.3 million, $5.1 million, and $5.0 million under the operating lease agreement for 60 Hampshire Street during the years ended December 31, 2025, 2024, and 2023, respectively.

As of December 31, 2025, the minimum lease payments for the Company's operating lease at 60 Hampshire Street for the next five years and thereafter are expected to be as follows:

Year Ending December 31,	Amount (in thousands)
2026	$ 5,409
2027	5,565
2028	5,726
2029	5,892
2030	6,063
Thereafter	9,403
Total lease payments	38,058
Less: interest	(8,691)
Present value of operating lease liabilities	$ 29,367

The remaining lease term and discount rate of the Company's operating lease at 60 Hampshire Street were 6.50 years and 8.0%, respectively, at December 31, 2025.

The remaining lease term and discount rate of the Company's operating lease at 60 Hampshire Street were 7.50 years and 8.0%, respectively, at December 31, 2024.

13. Income Taxes

During the years ended December 31, 2025, 2024, and 2023, the Company recorded no income tax benefits due to losses incurred and the uncertainty of future taxable income.

A reconciliation of the expected income tax (benefit) computed using the U.S. Federal statutory income tax rate to the Company's effective income tax rate is as follows for the years ended December 31, 2025, 2024, and 2023:

	December 31,					
	2025		2024		2023	
	Amount (in thousands)	Percentage	Amount (in thousands)	Percentage	Amount (in thousands)	Percentage
U.S. federal statutory tax rate	$ (58,061)	21.0%	$ (70,918)	21.0%	$ (71,814)	21.0%
State taxes, net of federal taxes	5	0.0%	(1)	0.0%	(2)	0.0%
Tax credits:						
Research and development	(8,416)	3.1%	(14,764)	4.4%	(12,996)	3.8%
Orphan drug	2,510	(0.9)%	(13,282)	3.9%	—	0.0%
Change in valuation allowance	52,747	(19.1)%	77,975	(23.1)%	79,661	(23.3)%
Nontaxable or nondeductible items						
Stock compensation	10,949	(4.0)%	22,658	(6.7)%	5,850	(1.7)%
Other	266	(0.1)%	(1,668)	0.5%	(699)	0.2%
Effective tax rate	$ —	0.0%	$ —	0.0%	$ —	0.0%

For the years ended December 31, 2025, 2024, and 2023, taxes in California comprised the majority of state taxes, net of federal taxes.

The Company's deferred tax assets and liabilities at December 31, 2025 and 2024, consist of the following:

	December 31,	
	2025	2024
	(in thousands)	
Deferred tax assets:		
Net operating losses	$ 235,130	$ 166,311
Tax credit carryforwards	96,552	88,707
Capitalized R&D	130,388	154,424
Lease liability	11,208	14,820
Stock compensation	15,659	16,892
Intangibles	1,728	1,341
Depreciation and amortization	619	967
Other	57	2,346
Total gross deferred tax assets	491,341	445,808
Valuation allowance	(480,517)	(431,929)
Net deferred tax assets	10,824	13,879
Deferred tax liabilities		
Operating lease assets	(10,824)	(13,879)
Total deferred tax liabilities	(10,824)	(13,879)
	$ —	$ —

The Company has incurred net operating losses ("NOLs") since inception. As of December 31, 2025 and 2024, the Company had federal NOL carryforwards of $923.9 million and $596.3 million, respectively, available to reduce federal taxable income, of which $43.1 million begin to expire in 2035 and $880.8 million do not expire. The Company also had state NOL carryforwards of $625.6 million and $625.2 million as of December 31, 2025 and 2024, respectively, available to reduce state taxable income, which begin to expire in 2035.

As of December 31, 2025 and 2024, the Company also had available federal research and development tax credit carryforwards of $55.9 million and $47.5 million, respectively, available to reduce federal tax liabilities, which begin to expire in 2035.

As of December 31, 2025 and 2024, the Company also had available state research and development tax credit carryforwards of $29.9 million and $27.0 million, respectively, available to reduce state tax liabilities, which being to expire in 2030.

As of December 31, 2025 and 2024, the Company also had available federal orphan drug tax credit carryforwards of $17.0 million and $19.5 million, respectively, available to reduce federal tax liabilities, which begin to expire in 2042.

Utilization of NOL and research and development credit carryforwards may generally be subject to limitation under Sections 382 and 383 of the Internal Revenue Code of 1986 ("Sections 382 and 383") due to ownership changes that have occurred previously or could occur in the future. Such ownership changes may limit the amount of NOL and research and development credit carryforwards that can be utilized annually to offset any post-ownership change in taxable income and tax, respectively. The most recent Section 382 study was performed by the Company up to December 31, 2025, through which it was noted that a historic ownership change has likely occurred. Nonetheless, the Company has concluded that, as of December 31, 2025, the prospective utilization of NOL and research and development credit carryforwards from inception through December 31, 2025 (and, therefore, the corresponding federal and state deferred tax assets) should not be restricted by Sections 382 and 383, although ownership changes after December 31, 2025 could impact the Company's ability to utilize such tax attributes in the future.

The Company recorded a valuation allowance against its deferred tax assets for the years ended December 31, 2025 and 2024, because the Company's management believes it is more likely than not that such assets will not be realized. The valuation allowance increased by $48.6 million and $132.1 million for the years ended December 31, 2025 and 2024, respectively, primarily as a result of operating losses generated with no corresponding financial statement benefit.

The Company had no unrecognized tax benefits as of December 31, 2025 and 2024.

The Company files tax returns, as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending tax examinations. The Company's tax years are still open under statute from inception to the present.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBB") was enacted in the U.S. The OBBB includes significant provisions, such as the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act ("TCJA") and restoration of favorable tax treatment for certain business provisions including the expensing of domestic research and development expenditures. The OBBB did not have a material impact on the Company's consolidated financial statements or footnotes.

14. Employee Benefits

In 2016, the Company established a defined-contribution plan under Section 401(k) of the Internal Revenue Code (the "401(k) Plan"). The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. The Company made matching contributions to the 401(k) Plan of $1.9 million, $2.4 million, and $2.6 million for the years ended December 31, 2025, 2024, and 2023, respectively.

15. Subsequent Events

In preparing the consolidated financial statements as of December 31, 2025, the Company evaluated subsequent events for recognition and measurement through the filing date of this Annual Report on Form 10-K. The Company concluded no events or transactions have occurred that require disclosure in the accompanying consolidated financial statements, except as otherwise included in the notes above.

EXHIBIT INDEX

Exhibit Number	Description
2.1†	Agreement and Plan of Merger dated April 15, 2021 by and among the Registrant, Elixir Merger Sub I, Inc., Elixir Merger Sub II, LLC, ZebiAI Therapeutics, Inc., and Shareholder Representative Services LLC (incorporated by reference to Exhibit 2.1 to the Registrant's Form 8-K (File No. 001-39385) filed on April 16, 2021).
3.1	Fourth Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Form 10-K (File No. 001-39385) filed on February 23, 2023).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Form 8-K (File No. 001-39385) filed on July 21, 2020).
4.1	Specimen stock certificate evidencing the shares of common stock (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1/A (File No. 333-239412) filed on July 9, 2020).
4.2	Description of Securities (incorporated by reference to Exhibit 4.2 to the Registrant's Form 10-K (File No. 001-39385) filed on February 22, 2024).
10.1#	2016 Stock Option and Grant Plan, and form of award agreements thereunder (incorporated by reference to Exhibit 10.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-239412) filed on June 24, 2020).
10.2#	2020 Stock Option and Incentive Plan, and form of award agreements thereunder (incorporated by reference to Exhibit 10.2 to the Registrant's Form 10-K (File No. 001-39385) filed on February 24, 2022).
10.3#	2020 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.3 of the Registrant's Registration Statement on Form S-1/A (File No. 333-239412) filed on July 9, 2020).
10.4#	Senior Executive Cash Bonus Plan (incorporated by reference to Exhibit 10.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-239412) filed on June 24, 2020).
10.5#	Amended and Restated Non-Employee Director Compensation Policy, effective as of May 8, 2025 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q (File No. 001-39385) filed on August 7, 2025).
10.6#	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.6 of the Registrant's Registration Statement on Form S-1 (File No. 333-239412) filed on June 24, 2020).
10.7#	Form of Amended and Restated Employment Agreement (incorporated by reference to Exhibit 10.8 of the Registrant's Registration Statement on Form S-1/A (File No. 333-239412) filed on July 9, 2020).
10.8#	Amended and Restated Employment Agreement, by and between the Registrant and Sanjiv K. Patel dated March 25, 2020 (incorporated by reference to Exhibit 10.9 of the Registrant's Registration Statement on Form S-1 (File No. 333-239412) filed on June 24, 2020).
10.9†	Amended and Restated Collaboration and License Agreement, by and between the Registrant and D. E. Shaw Research, LLC, dated June 15, 2020 (incorporated by reference to Exhibit 10.10 of the Registrant's Registration Statement on Form S-1 (File No. 333-239412) filed on June 24, 2020).
10.11†	Amendment No. AR1 to Amended and Restated Collaboration and License Agreement, by and between the Registrant and D. E. Shaw Research, LLC, dated February 4, 2021 (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-255583) filed with the SEC on April 28, 2021).
10.12	Amendment No. AR2 to Amended and Restated Collaboration and License Agreement, by and between the Registrant and D. E. Shaw Research, LLC, dated May 12, 2021 (incorporated by reference to Exhibit 10.4 to the Registrant's Form 10-Q (File No. 001-39385) filed on May 13, 2021).

10.13†	Amendment No. AR3 to Amended and Restated Collaboration and License Agreement, by and between the Registrant and D.E. Shaw Research, LLC, dated January 27, 2022 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q (File No. 001-39385) filed on May 5, 2022).
10.14†	Amendment No. AR4 to Amended and Restated Collaboration and License Agreement, by and between the Registrant and D.E. Shaw Research, LLC, dated March 22, 2023 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q (File No. 001-39385) filed on August 8, 2023).
10.15†	Amendment No. AR5 to Amended and Restated Collaboration and License Agreement, by and between the Registrant and D.E. Shaw Research, LLC, dated August 4, 2023 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q (File No. 001-39385) filed on November 2, 2023).
10.16	Registration Rights Agreement by and between the Registrant and the stockholders of ZebiAI Therapeutics, Inc. dated April 22, 2021 (incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1 (File No. 333-255583) filed on April 28, 2021).
10.17	Lease by and between the Registrant and BMR-Hampshire, LLC, dated May 26, 2021 (incorporated by reference to Exhibit 10.5 of the Registrant's Form 10-Q (File No. 001-39385) filed on August 12, 2021).
19.1	Registrant's Insider Trading Policy, dated December 13, 2024 (incorporated by reference to Exhibit 19.1 of the Registrant's Form 10-K (File No. 001-39385) filed on February 26, 2025).
21.1*	List of Subsidiaries of Registrant.
23.1*	Consent of Ernst & Young LLP, independent registered public accounting firm.
24.1*	Power of Attorney (included on signature page).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) or 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) or 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 and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Registrant's Compensation Recovery Policy, adopted as of September 29, 2023 (incorporated by reference to Exhibit 97.1 of the Registrant's Form 10-K (File No. 001-39385) filed on February 22, 2024).
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** The certifications furnished in Exhibit 32.1 hereto are deemed to accompany this Annual Report on Form 10-K and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

† Portions of this exhibit (indicated by asterisks) were omitted in accordance with the rules of Item 601(b)(10) of Regulation S-K.

# Indicates a management contract or any compensatory plan, contract or arrangement.

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**.**

Relay Therapeutics, Inc.

Date: February 26, 2026

By: /s/ Sanjiv K. Patel
Sanjiv K. Patel, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY AND SIGNATURES

Each person whose individual signature appears below hereby authorizes and appoints Sanjiv K. Patel, M.D. and Soo-Yeun Lim, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his or her substitute or substitutes may lawfully do or cause to be done by virtue thereof.

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.

Name	Title	Date
/s/ Sanjiv K. Patel Sanjiv K. Patel, M.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	February 26, 2026
/s/ Thomas Catinazzo Thomas Catinazzo	Chief Financial Officer (Principal Accounting Officer and Principal Financial Officer)	February 26, 2026
/s/ Alexis Borisy Alexis Borisy	Director	February 26, 2026
/s/ Linda A. Hill Linda A. Hill, Ph.D.	Director	February 26, 2026
/s/ Douglas S. Ingram Douglas S. Ingram	Director	February 26, 2026
/s/ Sekar Kathiresan Sekar Kathiresan, M.D.	Director	February 26, 2026
/s/ Mark Murcko Mark Murcko, Ph.D.	Director	February 26, 2026
/s/ Claire Mazumdar Claire Mazumdar	Director	February 26, 2026
/s/ Habib Dable Habib Dable	Director	February 26, 2026
/s/ Lonnel Coats Lonnel Coats	Director	February 26, 2026

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EXECUTIVE OFFICERS

Sanjiv K. Patel, M.D.
President and Chief Executive Officer

Thomas Catinazzo
Chief Financial Officer

Don Bergstrom, M.D., Ph.D.
President, Research & Development

Peter Rahmer
Chief Corporate Development Officer

BOARD OF DIRECTORS

Sanjiv K. Patel, M.D.

Sanjiv K. Patel, M.D. has served as a member of our board of directors and as our President and Chief Executive Officer since March 2017. Dr. Patel also served as a member of the board of directors of Prothena Corporation plc from May 2021 to July 2023 and ARYA Sciences Acquisition Corp V from July 2021 to July 2023, both of which are or were public companies. Before joining our company, Dr. Patel served in various roles at Allergan, Inc. from 2006 to 2017. He most recently served as Allergan's Executive Vice President, Chief Strategy Officer from March 2015 to March 2017 and previously as Corporate Vice President, Global Strategic Marketing and Global Health Outcomes from July 2013 to March 2015. Prior to this he was a management consultant at The Boston Consulting Group and practiced as a surgeon within the UK's National Health Service. Dr. Patel holds a MBBS from University of London, a M.A. in Medical Sciences from the University of Cambridge, a MRCS from the Royal College of Surgeons of England, and an MBA from INSEAD.

Linda A. Hill, Ph.D.

Linda A. Hill, Ph.D. has served as a member of our board of directors since October 2018. Dr. Hill is the Wallace Brett Donham Professor of Business Administration and Faculty Chair of the Leadership Initiative at the Harvard Business School, where she joined the faculty in July 1984, and is the author of several leadership books and articles. Her research focuses on building innovative organizations and ecosystems and the role of the board in governing innovation. Dr. Hill is also a Founding Partner of Paradox Strategies, a leadership and advisory firm. From 2000 to October 2018, Dr. Hill served as a member of the board of directors of State Street Corp., a publicly traded company. Dr. Hill is also a member of the board of directors of Brigham and Women's Hospital, the board of directors of Global Citizens Initiative, Inc., the board of trustees of the Art Center College of Design, the board of trustees of the Kresge Foundation and the Team8 Fintech Strategic Committee. She also serves on the Advisory Board of the Aspen Institute Business and Society Program, the Advisory Board for the California Institute for Telecommunications and Information Technology, the Advisory Board of Eight Inc., the Advisory Board for the Morgan Stanley Institute for Sustainable Investing and as a Commissioner for the National Association of Corporate Directors, Future of the American Boardroom. Dr. Hill holds a B.A. in psychology from Bryn Mawr College, and a M.A. in educational psychology and a Ph.D. in behavioral sciences from the University of Chicago.

Lonnel Coats

Lonnel Coats has served as a member of our board of directors since November 2025. Mr. Coats served as the Chief Executive Officer and a director of Lexicon Pharmaceuticals, Inc., or Lexicon, a biopharmaceutical company from 2014 to 2024. Prior to his time at Lexicon, from 1996 to 2014, Mr. Coats served in a series of leadership positions at Eisai Inc. and Eisai Corporation of North America, U.S. subsidiaries of Tokyo-based Eisai Co., Ltd., a Japanese pharmaceutical company, including as Chief Executive Officer of Eisai Inc. from 2010 to 2014 and as President and Chief Operating Officer of Eisai Inc. from 2004 to 2010. As President and Chief Executive Officer of Eisai, Mr. Coats oversaw the commercialization of Eisai products in the therapeutic areas of oncology, neurology, gastro-intestinal, epilepsy and metabolic disorders. Prior to joining Eisai, Mr. Coats spent eight years with Janssen Pharmaceuticals, Inc., a division of Johnson & Johnson, where he held a variety of management and sales positions. Mr. Coats is a former member of the board of directors of Blueprint Medicines Corporation and Verve Therapeutics, Inc., both formerly publicly traded biotechnology companies. Mr. Coats holds a B.S. in Public Administration from Oakland University.

Alexis Borisy

Alexis Borisy has served as the chairperson of our board of directors since our founding in April 2015 and served as interim Chief Executive Officer of our company from January 2016 to February 2017. He is the co-founder and Chairman of Curie.Bio, a venture capital firm focused on helping entrepreneurial founders launch therapeutics companies. From June 2019 to August 2021, Mr. Borisy served as Chief Executive Officer of EQRx, Inc., a biotechnology company, and from June 2019 to November 2023, Mr. Borisy served as chairman of EQRx, Inc. From 2010 to June 2019, Mr. Borisy was a partner at Third Rock Ventures, a series of venture capital funds investing in life science companies. Mr. Borisy co-founded Blueprint Medicines Corporation, a biopharmaceutical company, and served as its Interim Chief Executive Officer from 2013 to 2014 and served as a member of its board of directors from 2011 to July 2025, until its acquisition by Sanofi. Mr. Borisy co-founded Foundation Medicine, Inc. and served as its Interim Chief Executive Officer from 2009 to 2011 and served as a member of its board of directors from 2009 to July 2018, until its acquisition by Roche. In addition, during the past five years, Mr. Borisy has served as a member of the board of directors of various public companies, including Revolution Medicines, Inc., Magenta Therapeutics, Inc. and Tango Therapeutics, Inc., and private companies, including Celsius Therapeutics, Nextech Invest, Ltd., Ropirio Therapeutics, Inc., Delphia Therapeutics, Parabilis Medicines and Sesame Therapeutics, Inc. Mr. Borisy is the Vice-Chairman of the Board of Trustees of the Boston Museum of Science (formerly Chairman), and he previously served as Chairman of the National Venture Capital Association. Mr. Borisy received an A.B. in Chemistry from the University of Chicago and an A.M. in Chemistry and Chemical Biology from Harvard University.

Mark Murcko, Ph.D.

Mark Murcko, Ph.D is a co-founder of Relay Therapeutics and has served as a member of our board of directors since July 2016. Dr. Murcko was also our interim Chief Scientific Officer from February 2016 to December 2017. Since August 2020, Dr. Murcko has been serving as a member of the board of directors of Octant, Inc. and, since October 2021, has also served as Strategic Advisor thereof. Since August 2022, Dr. Murcko has been serving as a member of the board of directors of Myris Therapeutics (formerly known as BioHybrid Solutions, Inc.). Since July 2012, Dr. Murcko has been a senior lecturer in the Department of Biological Engineering at MIT. From November 2018 to July 2021, Dr. Murcko served as the Chief Innovation Officer of Dewpoint Therapeutics, Inc. and has been a member of the board of directors thereof since November 2018. Until November 2011, Dr. Murcko served as the Chief Technology Officer and chair of the scientific advisory board at Vertex Pharmaceuticals, Inc. and was responsible for the identification, validation and implementation of disruptive technologies across R&D. Dr. Murcko holds a B.S. in chemistry from Fairfield University and holds a Ph.D. in organic chemistry from Yale University.

Habib Joseph Dable

Habib Joseph Dable has served as a member of our board of directors since November 2025. Habib Dable has over 30 years of experience in the healthcare industry and is currently an advisor at RA Capital Management, L.P. Most recently, Mr. Dable was President and Chief Executive Officer of Acceleron Pharma Inc., a biopharmaceutical company targeting leading-edge therapies for patients with serious and rare diseases, from December 2016 until its acquisition by Merck in 2021. Prior to joining Acceleron in 2016, Mr. Dable spent 22 years at Bayer AG where he served as President of U.S. Pharmaceuticals; Executive Vice President, Global Head Specialty Medicine; Vice President, Ophthalmology; Global Launch Team Head, EYLEA®; Global Head, Neurology and Ophthalmology; and Vice President, Regional Head, Hematology and Cardiology. He has also served on the board of directors of Day One Biopharmaceuticals, Inc. since January 2024, PepGen Inc. since September 2022, and SpyGlass Pharma, Inc. since February 2026, each of which are publicly traded companies. Mr. Dable also serves on the board of directors of BioLink.org, a non-profit organization. Mr. Dable is also a former member of the board of directors of Blueprint Medicines Corporation, Millendo Therapeutics, Inc., Aerovate Therapeutics, Inc. and Albireo Pharma, Inc. Mr. Dable received a B.B.A and M.B.A. from the University of New Brunswick.

Douglas S. Ingram

Douglas S. Ingram has served as a member of our board of directors since June 2019. Mr. Ingram has served as President and Chief Executive Officer of Sarepta Therapeutics, Inc., a publicly traded biotechnology company, and a member of its board of directors since June 2017. From December 2015 until November 2016, he served as President and Chief Executive Officer of Chase Pharmaceuticals Corporation and as a member of its board of directors. Prior to joining Chase Pharmaceuticals, Mr. Ingram served as the President of Allergan, Inc. from July 2013 until it was acquired by Actavis in March 2015. At Allergan, he also served as President, Europe, Africa and Middle East from August 2010 to June 2013, and Executive Vice President, Chief Administrative Officer, and Secretary from October 2006 to July 2010. Mr. Ingram holds a B.S. from Arizona State University and a J.D. from the University of Arizona.

Sekar Kathiresan, M.D.

Sekar Kathiresan, M.D has served as a member of our board of directors since July 2022. Dr. Kathiresan is a co-founder of Verve Therapeutics, Inc., a biotechnology company, and served as its Chief Executive Officer and a member of its board of directors from July 2019 until its acquisition by Eli Lilly and Company in July 2025. He currently serves as Senior Vice President, Cardiometabolic Research, at Eli Lilly and Company. From April 2022 to November 2025, Dr. Kathiresan served as a member of the board of directors of Maze Therapeutics, Inc., a public biotechnology company. Dr. Kathiresan is currently an honorary physician at Massachusetts General Hospital, or MGH, and was an assistant physician at MGH from July 2005 to September 2021. Dr. Kathiresan served as director of the MGH Center for Genomic Medicine from April 2016 to June 2019. He also served as director of the Cardiovascular Disease Initiative at The Broad Institute from 2015 to June 2019 as well as an Institute Member at The Broad Institute from July 2019 to September 2021. He is currently a lecturer in medicine at Harvard Medical School and was a professor of medicine at Harvard Medical School from June 2018 to July 2021. Dr. Kathiresan holds a B.A. in history from the University of Pennsylvania and an M.D. from Harvard Medical School. He completed his clinical training in internal medicine and cardiology at MGH and his postdoctoral research training in human genetics at the Framingham Heart Study and The Broad Institute.

Claire Mazumdar, Ph.D.

Claire Mazumdar, Ph.D. has served as a member of our board of directors since June 2025. Dr. Mazumdar has served as the Chief Executive Officer and a director of Bicara Therapeutics, Inc., or Bicara, a public biotechnology company, since January 2020. Prior to joining Bicara, Dr. Mazumdar was the Head of Business Development and Corporate Strategy at Rheos Medicines, Inc., a biopharmaceutical company, from August 2017 to December 2019, which culminated in a large multi-target discovery partnership with Roche. Previously, Dr. Mazumdar was an investment professional at Third Rock Ventures, LLC, a life sciences venture capital firm, from July 2017 to July 2019. Dr. Mazumdar is a member of the board of directors for Noora Health, a global non-profit. Dr. Mazumdar received a BS in Biological Engineering from Massachusetts Institute of Technology, a Ph.D. in Cancer Biology from Stanford School of Medicine, and an M.B.A. from Stanford Graduate School of Business.

CORPORATE INFORMATION

Corporate Headquarters
60 Hampshire Street
Cambridge, MA 02139

Transfer Agent
Computershare Trust Company, N.A.
P.O. Box 43006
Providence, RI 02940

Independent Registered Public Accounting Firm
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