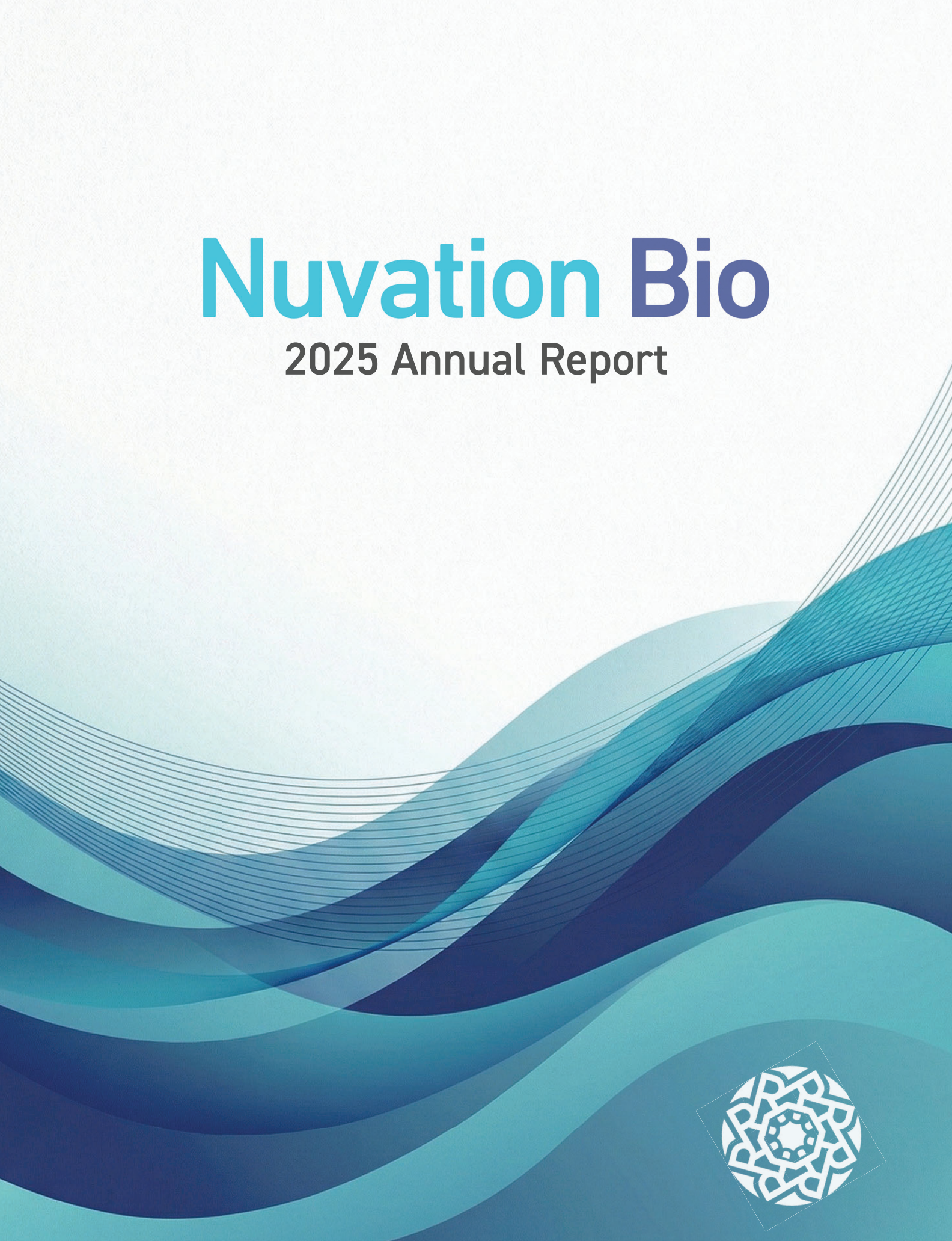
Nuvation Bio

2025 Annual Report



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 001-39351

NUVATION BIO INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**85-0862255**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1500 Broadway, Suite 1401 New York, New York	**10036**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (332) 208-6102

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A Common Stock, Par Value $0.0001 Per Share	**NUVB**	**New York Stock Exchange**

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 Exchange 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 Exchange Act 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act:

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

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

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

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

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

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

The aggregate market value of the voting common stock, par value $0.0001 per share, held by non-affiliates of the registrant computed by reference to the closing sales price for the registrant’s common stock on June 30, 2025, as reported on the New York Stock Exchange was approximately $496,965,132.

In determining the market value of the voting stock held by any non-affiliates, shares of common stock of the registrant beneficially owned by directors and officers have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 26, 2026, the registrant had 346,597,289 shares of Class A common stock and 1,000,000 shares of Class B common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

Certain portions of the registrant's definitive proxy statement relating to the Company's Annual Meeting of Stockholders, to be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2025, are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated.

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CAUTIONARY INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the year ended December 31, 2025, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by those sections, concerning our business, operations, and financial performance and condition as well as our plans, objectives, and expectations for business operations and financial performance and condition. Any statements contained herein that are not of historical facts may be deemed to be forward-looking statements. You can identify these statements by words such as "anticipate," "assume," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would," or the negative of these terms or other similar expressions that are predictions of or indicate future events and future trends. These forward-looking statements are based on current expectations, estimates, forecasts, and projections about our business and the industry in which we operate and management's beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties, and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Annual Report on Form 10-K may turn out to be inaccurate. Factors that could materially affect our business operations and financial performance and condition include, but are not limited to, those risks and uncertainties described herein under "Item 1A—Risk Factors." You are urged to consider these factors carefully in evaluating the forward-looking statements and are cautioned not to place undue reliance on the forward-looking statements. The forward-looking statements are based on information available to us as of the filing date of this Annual Report on Form 10-K. Unless required by law, we do not intend to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise. You should, however, review the factors and risks we describe in the reports we will file from time to time with the Securities and Exchange Commission, or the SEC, after the date of this Annual Report on Form 10-K.

SUMMARY RISK FACTORS

Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found in the section titled "*Risk Factors*" in Item 1A of this Annual Report on Form 10-K. The below summary is qualified in its entirety by that more complete discussion of such risks and uncertainties. You should consider carefully the risks and uncertainties described in the section titled *"Risk Factors*" as part of your evaluation of an investment in our securities:

- Our near-term prospects are significantly dependent on the commercialization of IBTROZI® (talectrectinib). If we are unable to successfully commercialize IBTROZI, our ability to generate meaningful revenue or achieve profitability will be materially and adversely affected.
- We have limited experience as a commercial company and our sales, marketing, and distribution of IBTROZI may be unsuccessful or less successful than anticipated.
- If the market opportunities for IBTROZI are smaller than we believe, our revenue may be adversely affected, and our business may suffer.
- IBTROZI may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.
- The successful commercialization of IBTROZI and our other product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels and pricing policies. Failure to obtain or maintain adequate coverage and reimbursement for IBTROZI or our other product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.
- If competitors develop products, product candidates or technologies that are superior to or more cost-effective than IBTROZI, it would significantly impact the development and commercial viability of IBTROZI, which would severely and adversely affect our financial results, business and business prospects, and the future of IBTROZI, and might cause us to cease operations.

- We rely on a select network of third-party distributors, specialty pharmacies and other vendors to distribute IBTROZI in the U.S., and any failure by such distributors, specialty pharmacies and vendors could adversely affect our revenues, financial condition, or results of operations.
- If we are unable to maintain agreements with third parties to sell and market taletrectinib in jurisdictions outside of the U.S. or our partnered territories, we will be unable to successfully commercialize taletrectinib if and when it is approved in such jurisdictions.
- Failure by us to maintain a manufacturing supply chain to appropriately and adequately supply IBTROZI for commercial and future clinical uses would adversely affect our ability to commercialize IBTROZI and/or result in a further delay in or cessation of clinical trials, and our business and business prospects could be severely harmed.
- We may be unable to maintain regulatory approval for IBTROZI in the U.S. or other jurisdictions, which would severely and adversely affect our business and business prospects.
- If we or others later discover that IBTROZI or any of our future approved product candidates is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market such approved drug could be compromised.
- Our regulatory approvals for taletrectinib in the U.S. and China for advanced ROS1+ NSCLC are subject to certain post-marketing requirements and/or commitments, and we may be subject to penalties or product withdrawal if we fail to comply with these regulatory requirements and commitments or if we experience unanticipated problems with taletrectinib.
- If we do not obtain regulatory approval for and successfully commercialize additional product candidates or we experience significant delays in doing so, we may incur significant losses.
- Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors and customers are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, health information privacy and security laws and other healthcare laws and regulations, including comparable foreign healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.
- We do not have our own manufacturing capabilities and will rely on third parties to produce clinical and commercial supplies of taletrectinib, safusidenib, and our other current and future product candidates.
- We will need substantial funding to pursue our business objectives. If we are unable to receive significant revenues from the sales of our products or if we are unable to raise capital if and when needed or on favorable terms, we could be forced to delay, reduce or terminate our product development, other operations or commercialization efforts.
- Our level of indebtedness and debt service obligations could adversely affect our financial condition and may make it more difficult for us to fund our operations.
- We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.
- Clinical trials are very expensive, time-consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- Our approach to the discovery and development of product candidates based on our Drug-Drug Conjugate platform is unproven, and we do not know whether we will be able to develop any products of commercial value, or if competing technological approaches will limit the commercial value of our product candidates or render our platform obsolete.

- We rely on third parties to perform the chemistry work associated with our drug discovery and preclinical activities and to conduct our preclinical studies and future clinical trials, and our business could be substantially harmed if these third parties cease performing services or perform in an unsatisfactory manner.
- If we are unable to obtain, maintain, protect and enforce sufficient patent and other intellectual property rights for our product candidates and technology, or if the scope of patent and other intellectual property rights obtained is not sufficiently broad, we may not be able to compete effectively in our market.
- Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.
- We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful, and issued patents covering our technology and product candidates could be found invalid or unenforceable if challenged.
- Our business, operations and clinical development plans and timelines and supply chain could be adversely affected by the effects of health epidemics, on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our contract manufacturing organizations ("CMOs"), contract research organizations ("CROs"), shippers and others.
- Our future success depends on our ability to retain Dr. Hung and our other key employees, consultants and advisors and to attract, retain and motivate qualified personnel.
- The dual-class structure of our Common Stock has the effect of concentrating voting power with our Chief Executive Officer, which limits other stockholders' ability to influence the outcome of important transactions, including a change in control.

PART I

Item 1. Business.

On February 10, 2021, (the "Closing Date"), Nuvation Bio Inc., a Delaware corporation ("Legacy Nuvation Bio"), Panacea Acquisition Corp. ("Panacea"), and Panacea Merger Subsidiary Corp, a Delaware corporation and a direct, wholly owned subsidiary of Panacea ("Merger Sub") consummated the transactions contemplated by an Agreement and Plan of Merger among them dated October 20, 2020 ("Merger Agreement").

Pursuant to the terms of the Merger Agreement, a business combination of Panacea and Legacy Nuvation Bio was effected through the merger of Merger Sub with and into Legacy Nuvation Bio, with Legacy Nuvation Bio surviving as a wholly owned subsidiary of Panacea (the "Merger"). On the Closing Date, Legacy Nuvation Bio changed its name to Nuvation Bio Operating Company Inc. and Panacea changed its name to Nuvation Bio Inc. (the "Company" or "Nuvation Bio").

In connection with the closing of the Merger, our Class A common stock and warrants to purchase shares of our Class A common stock began trading on The New York Stock Exchange under the symbols "NUVB" and "NUVB.WS," respectively, on February 11, 2021. The disclosure in Items 1 and 1A of this report gives effect to the Merger and includes the operations of Legacy Nuvation Bio prior to the Merger.

On April 9, 2024 (the "Acquisition Date"), the Company completed its acquisition of AnHeart Therapeutics Ltd., an exempted company incorporated under the laws of the Cayman Islands ("AnHeart"), pursuant to that certain Agreement and Plan of Merger (the "AnHeart Merger Agreement"), by and among the Company, AnHeart, Artemis Merger Sub I, Ltd., an exempted company incorporated under the laws of the Cayman Islands and a wholly owned

subsidiary of the Company, and Artemis Merger Sub II, Ltd., an exempted company incorporated under the laws of the Cayman Islands and a wholly owned subsidiary of the Company.

"Nuvation Bio" is a registered trademark of Nuvation Bio Inc. in the U.S. and other countries. Other trademarks or service marks appearing in this report may be trademarks or service marks of other owners.

Business Overview

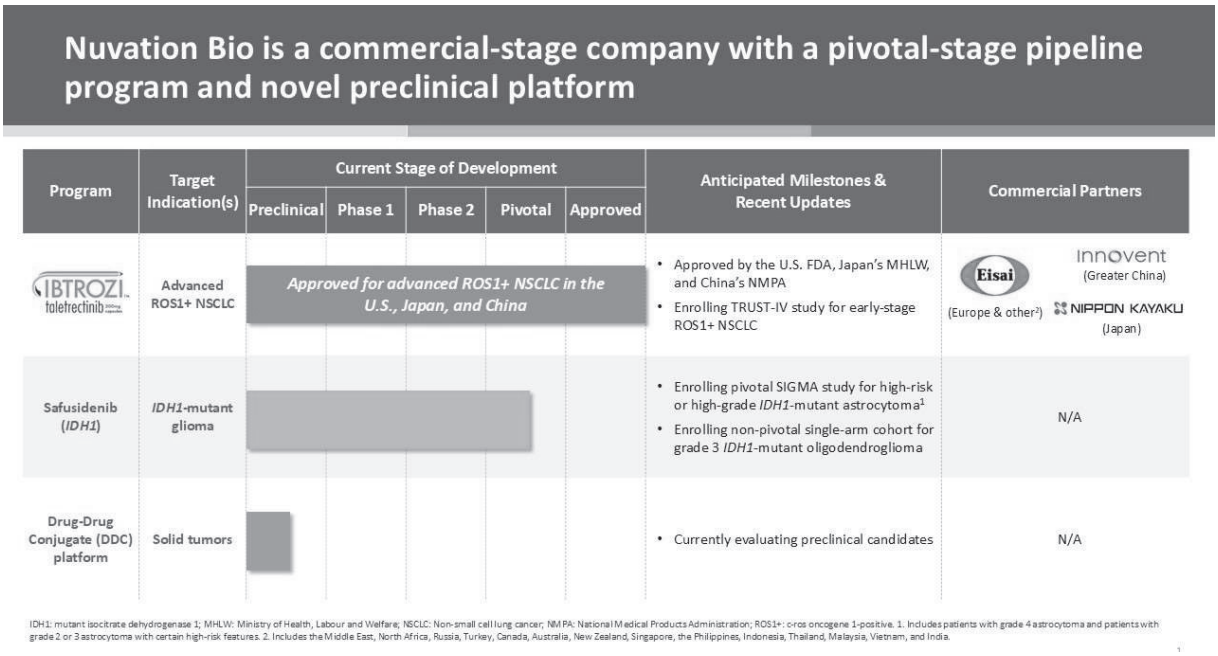
We are a global oncology company focused on tackling some of the toughest challenges in cancer treatment with the goal of developing therapies that create a profound, positive impact on patients' lives. We were founded in 2018 by our chief executive officer, David Hung, M.D., who founded Medivation, Inc. and led its successful development of oncology drugs Xtandi® and talazoparib (now marketed as Talzenna®), leading to its $14.3 billion sale to Pfizer Inc. ("Pfizer") in 2016.

We leverage our team's extensive expertise in medicinal chemistry, preclinical development, drug development, business development, manufacturing, and commercialization to pursue oncology targets validated by strong clinical or preclinical data and develop novel small molecules that improve the activity and overcome the liabilities of currently marketed drugs.

The foundations of our approach include:

- ***The pursuit of validated targets:*** We identify and pursue oncology targets validated by strong clinical or preclinical data that provide a high degree of confidence in generating clinically meaningful benefit. We focus on targets where there has been some progress by others in generating clinical candidates or approved drugs, and we then attempt to design or acquire novel or potential best-in-class product candidates to overcome the encountered safety liabilities or limitations in efficacy.
- ***Innovative medicinal chemistry expertise:*** We use our medicinal chemistry proficiency to generate differentiated product candidates, focused on improving their safety, anti-tumor activity and pharmacologic profiles over other standard of care ("SOC") therapies. We also use innovative medicinal chemistry approaches to generate novel classes of molecules such as our drug-drug-conjugates ("DDCs").
- ***Human capital management***: We believe our employees are our greatest assets. Attracting, motivating and retaining talent at all levels is vital to our continued success. We are building a culture that fosters a productive, professional and inclusive work environment, where people can thrive, have fun, and be inspired to perform their best work.

The following table summarizes our product candidate pipeline:



We commercially launched IBTROZI in the U.S. in June 2025, following its approval by the U.S. Food and Drug Administration ("FDA") on June 11, 2025 for the treatment of adult patients with locally advanced or metastatic ROS1-positive ("ROS1+") non-small cell lung cancer ("NSCLC"). Taletrectinib has also been approved by Japan's Ministry of Health, Labour, and Welfare ("MHLW") and by China's National Medical Products Administration ("NMPA") for the treatment of adult patients with ROS1+ locally advanced or metastatic NSCLC ("mNSCLC"). Taletrectinib is being commercialized in Japan by our partner Nippon Kayaku Co., Ltd ("NK") under the brand name IBTROZI and in China by our partner Innovent Biologics (Suzhou) Co. Ltd. ("Innovent") under the brand name DOVBLERON®. Taletrectinib has been granted Orphan Drug Designation by the U.S. FDA for the treatment of patients with ROS1+ NSCLC and other NSCLC indications and was previously granted Breakthrough Therapy Designations by both the U.S. FDA and China's NMPA for the treatment of patients with locally advanced or metastatic ROS1+ NSCLC. In January 2026, we announced a partnership with Eisai Co., Ltd. ("Eisai") to commercialize taletrectinib in Europe and other territories outside the U.S., China and Japan. In partnership with Eisai, we expect to submit a Marketing Authorization Application ("MAA") to the European Medicines Agency ("EMA") in the first half of 2026.

Taletrectinib continues to be evaluated for the treatment of patients with locally advanced or metastatic ROS1+ NSCLC in two Phase 2 single-arm pivotal studies: TRUST-I in China, and TRUST-II, a global study, as well as in a confirmatory randomized Phase 3 study versus crizotinib in China known as TRUST-III. In September 2025, we announced our first patient was enrolled in a global Phase 3, placebo-controlled study known as TRUST-IV, to evaluate taletrectinib for the adjuvant treatment of patients with resected ROS1+ early-stage NSCLC.

In addition to taletrectinib, our clinical stage pipeline includes safusidenib, a novel, oral, potent, brain penetrant, targeted inhibitor of mutant isocitrate dehydrogenase 1 ("mIDH1"). Safusidenib is being evaluated in the SIGMA study, which is a randomized Phase 3 study for the maintenance treatment of high-risk or high-grade IDH1-mutant astrocytoma with safusidenib against placebo.

Strategy

We strive to deliver meaningful benefits to patients with serious unmet medical needs in oncology by developing and commercializing novel and differentiated therapies. The core elements of our strategy include:

- Maximize the value of IBTROZI, including continued investment and execution of our U.S. commercial launch in ROS1+ mNSCLC, and supporting the ongoing development and commercialization efforts of our collaboration partners Innovent, NK, and Eisai in their respective licensed territories.
- Advancing the ongoing clinical development of safusidenib and continued evaluation of preclinical candidates from our drug-drug conjugate (DDC) platform.
- Leveraging our deep insights in medicinal chemistry to pursue innovative clinical candidates and our business development expertise to identify and in-license or acquire additional promising drug candidates.
- Identifying strategic opportunities to accelerate development timelines and maximize the value of our pipeline.

U.S. Commercialization of IBTROZI

IBTROZI is an oral, potent, central nervous system-active, selective, next-generation ROS1 inhibitor. On June 11, following Priority Review and Breakthrough Therapy Designations for both TKI-naïve and TKI-pretreated disease, the U.S. Food and Drug Administration ("FDA") approved IBTROZI for the treatment of adult patients with locally advanced or metastatic ROS1+ NSCLC.

We believe IBTROZI is becoming the new standard of care in advanced ROS1+ NSCLC, which is supported by IBTROZI's best-in-class efficacy and safety profile including objective response rate, durable responses, prolonged progression-free survival, brain penetrance to improve outcomes for patients with brain metastases, activity against tumors that have developed resistance mutations to approved ROS1 tyrosine kinase inhibitors ("TKIs") such as G2032R, and a low rate of treatment discontinuation.

As the potential new standard of care in advanced ROS1+ NSCLC, we believe the market opportunity for IBTROZI is significant. Each year, more than one million people globally are diagnosed with NSCLC, the most common form of lung cancer. It is estimated that approximately 2% of patients with NSCLC have ROS1+ disease (Lin et al 2017; Zhang et al 2019). Up to 35% of patients newly diagnosed with metastatic ROS1+ NSCLC have tumors that spread to their brain, increasing up to 55% for those whose cancer has progressed following initial treatment (Ou et al 2019).

To support this significant market opportunity, we have 71 commercial field team members, including key account managers and national account teams, along with 7 medical affairs field team members. We offer a wide range of resources to support access and affordability for eligible IBTROZI patients, including our Nuvation Connect™ patient support program, which provides a range of resources, including field reimbursement support, which are designed to support access and affordability to eligible patients prescribed IBTROZI.

Taletrectinib Development Programs

IBTROZI Pivotal Studies Overview

IBTROZI's regulatory approval in the U.S. for the treatment of adult patients with locally advanced or metastatic ROS1+ NSCLC is based on positive data from two pivotal Phase 2 single-arm studies: TRUST-I in China, and TRUST-II, a global study. With nearly 300 patients enrolled in TRUST-I and TRUST-II, these pivotal studies represent one of the largest global clinical trial programs to date in locally advanced or metastatic ROS1+ NSCLC.

IBTROZI's FDA approved label is based on an October 2024 data cutoff for TRUST-I and TRUST-II. In TRUST-I, IBTROZI achieved a confirmed objective response rate ("cORR") of 90% in TKI-naïve patients. These findings were reinforced by the TRUST-II results, with a cORR of 85% in TKI-naïve patients. At the time of the October 2024 data cutoff, the median duration of response ("DOR") had not been reached in either study. However, based on a more recent August 2025 data cutoff, we announced that IBTROZI's median DOR in the pooled TRUST-I and TRUST-II studies had matured to 50 months. We plan on providing additional data from the August 2025 data cutoff at a medical conference in 2026.

Across the TRUST-I and TRUST-II pivotal studies, consistent results were also observed among patients who were previously treated with a ROS1 TKI ("TKI-pretreated"). As of the October 2024 data cutoff, in TRUST-I, treatment with IBTROZI achieved a cORR of 52% and median DOR of 13.2 months for TKI-pretreated patients, with median follow-up for responses of 33 months. In TRUST-II, treatment with IBTROZI achieved a cORR of 62%, and as of October 2024, the median DOR was 19.4 months in these patients, with a median follow-up for responses of 19 months.

IBTROZI was generally well-tolerated, with most adverse events being low grade, transient and manageable. Patients infrequently (7%) discontinued treatment due to treatment-emergent adverse events ("TEAEs"). The most common adverse reactions (≥20%) included diarrhea (64%), nausea (47%), vomiting (43%), dizziness (22%), rash (22%), constipation (21%), and fatigue (20%). Overall, the majority of central nervous system events were mild to moderate (~90%) and resolved within days, and dose modifications due to these events were low (~5%). Approximately 90% of reported cases of dizziness were Grade 1 (mild) and transient. Liver enzyme elevations (AST 87%/ALT 85%) and QT prolongation (19%) were manageable with standard monitoring and dose modifications.

Additional Clinical Studies

We are also evaluating taletrectinib in a confirmatory randomized Phase 3 study versus crizotinib in China for treatment naïve patients with locally advanced or metastatic ROS1+ NSCLC, which is known as TRUST-III, as well as in a global Phase 3, placebo-controlled study for the adjuvant treatment of patients with resected ROS1+ early-stage NSCLC, which is known as TRUST-IV.

Taletrectinib In-License Agreement

In December 2018, AnHeart Therapeutics Inc. ("AHT"), a wholly owned subsidiary of AnHeart, entered into a license agreement with Daiichi Sankyo Company, Limited ("Daiichi Sankyo"), pursuant to which Daiichi Sankyo granted to AHT exclusive worldwide rights to develop and commercialize taletrectinib (the "Taletrectinib In-License Agreement").

To date, under the Taletrectinib In-License Agreement, we have paid Daiichi Sankyo $23.0 million in connection with an upfront payment and the achievement of development and regulatory milestones. In addition, we are obligated to pay up to $20.0 million upon achievement of commercial sales milestones, and a high single-digit percentage royalty based on worldwide net sales subject to certain adjustments. Our obligation to pay royalties under the Taletrectinib In-License Agreement will expire on a country-by-country basis upon the later of the expiration of the last valid claim of a patent licensed under the Taletrectinib In-License Agreement covering taletrectinib, and ten years after the first commercial sale of taletrectinib in such country.

The Taletrectinib In-License Agreement will continue in effect until we cease all commercial activity related to taletrectinib. We may terminate the Taletrectinib In-License Agreement on a country-by-country basis or in its entirety upon 6 months prior written notice if we have bona fide material concerns regarding the lack of efficacy of taletrectinib, if patent claim(s) covering taletrectinib are invalidated in the relevant jurisdiction, or if taletrectinib is determined to infringe one or more claims of a third-party patent. Daiichi Sankyo may terminate the Taletrectinib In-License Agreement due to our insolvency or bankruptcy, or if we challenge any patents licensed under the Taletrectinib In-License Agreement. Either party may terminate the agreement in the event of a material breach by the other party that remains uncured for 90 days (or, if such material breach cannot be cured within 90 days, if the other party does not commence and diligently continue actions to cure such breach during such 90 days).

We need Daiichi Sankyo's prior written consent to grant sublicenses under the rights licensed to us under the Taletrectinib In-License Agreement, provided that any denial of approval by Daiichi Sankyo must be made in good faith based on reasonable concerns. Furthermore, under certain circumstances, we need Daiichi Sankyo's prior consent to assign our rights under the Taletrectinib In-License Agreement.

Taletrectinib Out-License Agreements

In May 2021, Nuvation Bio China Ltd. (formerly known as AnHeart Therapeutics (Hangzhou) Co. Ltd.) ("Nuvation Bio China"), a wholly owned subsidiary of AnHeart, entered into a collaboration and license agreement with Innovent (the "Innovent Agreement"), pursuant to which Nuvation Bio China granted to Innovent exclusive rights to commercialize taletrectinib in mainland China, Hong Kong, Macau and Taiwan (collectively, the "Innovent Territory"), as well as certain development rights within the Innovent Territory. To date, pursuant to the Innovent

Agreement, Nuvation Bio China has received $67.0 million in connection with an upfront payment, reimbursement of research and development expenses, and achievement of regulatory milestones. In addition, we may receive up to $17.0 million upon achievement of additional regulatory milestones, up to $105.0 million upon achievement of commercial milestones, and tiered percentage royalties ranging from mid-teen to low-twenties on annual net sales of taletrectinib in the Innovent Territory subject to certain adjustments. Innovent's obligation to pay royalties under the Innovent Agreement will expire on a country-by-country basis upon the later of the expiration of the last valid claim of a patent licensed under the Taletrectinib In-License Agreement covering taletrectinib, and ten years after the first commercial sale of taletrectinib in such country. The Innovent Agreement will continue in effect until Innovent ceases all commercial activity related to taletrectinib in the Innovent Territory or termination of the Taletrectinib In-License Agreement. We may terminate the Innovent Agreement if Innovent challenges any patents licensed to it under the Innovent Agreement. Innovent may terminate the Innovent Agreement upon one-month's prior written notice if it has bona fide material concerns regarding the lack of safety or efficacy of taletrectinib. Either party may terminate the agreement in the event of a material breach by the other party that remains uncured for 90 days (or, if such material breach cannot be cured within 90 days, if the other party does not commence and diligently continue actions to cure such breach during such 90 days), or due to insolvency or bankruptcy of the other party.

In October 2023, AHT entered into a collaboration and license agreement with NK (the "NK Agreement"), pursuant to which AHT granted to NK exclusive rights to commercialize taletrectinib for all human indications in Japan (the "NK Territory"), and exclusive rights to research and develop taletrectinib for any indication other than ROS1+ NSCLC in Japan subject to AnHeart's prior approval. Pursuant to the NK Agreement, AHT received a $40.0 million upfront payment. In addition, we received $25.0 million upon achievement of a regulatory milestone and may receive up to $35.0 million upon achievement of commercial milestones, and a lower-mid double digit percentage royalty on net sales of taletrectinib in the NK Territory. The NK Agreement will continue in effect until the later of first sale of a first generic for taletrectinib for which a drug reimbursement price has been established in the NK Territory, and our obligation to pay royalties under the Taletrectinib In-License Agreement for net sales of taletrectinib in the NK Territory. We may terminate the NK Agreement if NK challenges any patents licensed to it under the NK Agreement. NK may terminate the NK Agreement upon 90 days prior written notice if it has bona fide material concerns regarding the lack of safety or efficacy of taletrectinib, or at any time after first commercial sale of taletrectinib upon 6 month's prior written notice. Either party may terminate the agreement in the event of a material breach by the other party that remains uncured for 90 days (or, if such material breach cannot be cured within 90 days, if the other party does not commence and diligently continue actions to cure such breach during such 90 days), and AHT may terminate the agreement due to insolvency or bankruptcy of NK.

In January 2026, we entered into a license and collaboration agreement (the "Eisai Agreement") with Eisai, pursuant to which we granted Eisai an exclusive license to develop and commercialize taletrectinib in the following territories: the European Union and all member states thereof, Albania, Andorra, Armenia, Azerbaijan, Belarus, Bosnia and Herzegovina, Georgia, Kosovo, Moldova, Monaco, Montenegro, North Macedonia, San Marino, Serbia, Switzerland, Ukraine, Vatican City, the United Kingdom, Russia, Turkey, Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, the United Arab Emirates, Israel, Jordan, Iran, Iraq, Libya, Lebanon, Egypt, Sudan, Morocco, Algeria, Tunisia, Australia, New Zealand, Canada, Singapore, Philippines, Indonesia, Thailand, Malaysia, Vietnam and India (collectively, the "Eisai Territory"). Pursuant to the Eisai Agreement, we received a €50 million upfront payment. In addition, we may receive a regulatory milestone of €25 million and up to an aggregate of €120 million upon the achievement of certain sales milestones, and tiered percentage royalties ranging from low- to high-teens on aggregate annual net sales of taletrectinib subject to certain customary reductions. Eisai's obligation to pay royalties under the Eisai Agreement will expire on a country-by-country basis upon the later of the expiration of the last valid claim of licensed patents covering taletrectinib, the expiration of regulatory exclusivity covering taletrectinib, and ten years after the first commercial sale of taletrectinib in such country. The Eisai Agreement will continue in force until the expiration of the applicable royalty term. We may terminate the Eisai Agreement if Eisai challenges any patents licensed to it under the Eisai Agreement. Eisai may terminate the Eisai Agreement if we materially breach or terminate the Taletrectinib In-License Agreement, if taletrectinib has a demonstrated lack of safety for human use due to significant toxicity that was unknown as of the effective date of the Eisai Agreement, if Eisai does not receive certain regulatory approvals from the European Commission by a certain date (except where such failure is as a result of Eisai's acts or omissions), or on a country-by-country basis if certain fundamental patents are invalidated in such country in the Territory. Either party may terminate the Eisai Agreement in the event of a material breach by the other party that remains uncured for 90 days (or, if such material breach cannot be cured within 90 days, if the other party does not commence and diligently continue actions to cure such breach during such 90 days or if the material breach remains uncured for 180 days), or due to insolvency or bankruptcy of the other party.

Safusidenib: mIDH1 Inhibitor Program

Safusidenib is a novel, oral, potent, brain penetrant, targeted inhibitor of mIDH1, which is detected in various tumors, including gliomas. IDH proteins play a critical role in the citric acid cycle, also known as the tricarboxylic acid cycle or Krebs cycle, by catalyzing the conversion of isocitrate to α-ketoglutarate. Mutant IDH catalyzes abnormal conversion of α-ketoglutarate to the oncometabolite 2-hydroxyglutarate (2-HG). Accumulation of 2-HG leads to tumorigenesis by inducing changes in various cellular processes, including epigenetic dysregulation. Most patients with IDH mutant glioma harbor the mIDH1 subtype known as IDH1R132H (Machida et al 2020). The Central Brain Tumor Registry of the United States estimated that the incidence of IDH-mutant glioma in the United States in 2018-2021 to be approximately 2,500 new cases per year, with approximately half of such patients classified as low-grade and the other half as high-grade.

Safusidenib has high blood–brain barrier ("BBB") permeability and inhibits mIDH1, including the subtype IDH1R132H. Continuous administration of safusidenib impaired tumor growth and decreased 2-HG levels in subcutaneous and intracranial xenograft models derived from a patient with mIDH1-positive glioblastoma. Moreover, the expression of glial fibrillary acidic protein was strongly induced by safusidenib, suggesting that inhibition of mIDH1 promotes glial differentiation (Machida et al 2020).

Phase 1 Study Results

A Phase 1 multicenter, open-label, dose-escalation study evaluating safusidenib as a monotherapy in 47 patients was conducted in Japan and sponsored by Daiichi Sankyo Co., Ltd. Patients were divided into enhancing and non-enhancing groups based on the presence or absence of tumor contrast enhancement judged by each investigator at the time of enrollment. Tumor response was assessed by Response Assessment in Neuro-Oncology ("RANO") for enhancing tumors and RANO-low grade glioma ("RANO-LGG") for non-enhancing tumors. Tumors that show enhancement on MRI scans tend to have more vascularization and disruption to the blood-brain barrier and are generally associated with a higher degree of malignancy compared with non-enhancing tumors.

As reported in the journal of *Neuro-Oncology* in February 2023, the objective response rates were 17.1% for enhancing tumors and 33.3% for non-enhancing tumors, including one complete response in a grade 4 astrocytoma and one complete response in the target lesions of a grade 3 oligodendroglioma (with stable disease in non-target lesions).

The maximum tolerated dose was not reached. Most adverse events (AEs) were grade 1-2. Twenty (42.6%) patients experienced at least one grade 3 AE. No grade 4 or 5 AEs or serious drug-related AEs were reported. Common AEs (>20%) were skin hyperpigmentation, diarrhea, pruritus, alopecia, arthralgia, nausea, headache, rash, back pain, and dry skin. Seven on-treatment brain tumor samples showed a significantly lower amount of D-2-HG compared with pre-study archived samples.

Japan Phase 2 Study Results

Safusidenib is being evaluated in a Phase 2 open-label, multicenter, single-arm study in 27 patients with *IDH1*-mutant grade 2 gliomas who had no prior anticancer therapy except for resection or biopsy. This study is being conducted in Japan by Daiichi Sankyo.

As reported in the journal of *Neuro-Oncology* in November 2025, the study met its primary endpoint, demonstrating an objective response rate ("ORR") of 44.4%; median duration of response could not be estimated because no progression events had occurred. As of the data cut-off (March 2023), median progression-free survival ("PFS") was not yet reached, with a median follow-up time of 28 months, demonstrating the long-term potential of safusidenib to delay disease progression. At 24 months, 87.9% of patients were progression free. While the published results reflect the March 2023 data cutoff, as of September 2025, 12 patients remained on treatment with safusidenib, further supporting the durability of responses.

Adverse events were mostly mild to moderate and manageable. Grade 3 or greater treatment-related adverse events occurred in five (18.5%) patients. No grade 5 events were reported. Three (11.1%) patients had treatment-emergent adverse events that led to study treatment discontinuation, two of which were considered related to safusidenib by study investigators and were resolved with dose interruption and/or appropriate medical management.

It should be noted that a Good Clinical Practice ("GCP") noncompliance issue regarding the collection of adverse events was identified during the study. Therefore, all safety data presented in this manuscript was based on a

subsequent re-investigation and re-collection of adverse events performed in strict accordance with the study protocol to ensure data integrity.

Clinical Development Plan for Safusidenib in mIDH1 Glioma

We are currently conducting a Phase 3 global study to evaluate the efficacy and safety of safusidenib versus placebo for the maintenance treatment of patients with high-risk or high-grade IDH1-mutant astrocytoma following standard-of-care, which is known as the SIGMA study. The primary endpoint is PFS as assessed by Blinded Independent Central Review per Response Assessment in Neuro-Oncology 2.0, which the FDA agreed could support full approval in this setting. Secondary endpoints include overall survival, PFS as assessed by the investigator, ORR, and duration of response. The enrollment target for this pivotal cohort is 300 patients. The trial will also enroll a separate, non-pivotal, single-arm cohort to examine the efficacy and safety of safusidenib in patients with chemotherapy and radiotherapy naïve grade 3 IDH1-mutant oligodendroglioma. The primary endpoint for this exploratory cohort is ORR. This cohort will enroll approximately 40 patients.

Safusidenib In-License Agreement

In September 2020, AHT entered into a license agreement with Daiichi Sankyo, pursuant to which Daiichi Sankyo granted to AHT exclusive worldwide (other than Japan) rights to develop and commercialize safusidenib for all human prophylactic or therapeutic uses (the "Safusidenib In-License Agreement"). Daiichi Sankyo retains the right to develop and commercialize safusidenib in Japan.

To date, under the Safusidenib In-License Agreement, AHT has paid Daiichi Sankyo $12.0 million in connection with an upfront payment and the achievement of a development milestone. In addition, we are obligated to pay up to $3.0 million upon achievement of additional development milestones, up to $50.0 million upon achievement of regulatory milestones, up to $45.0 million upon achievement of commercial sales milestones, and a high single-digit percentage royalty based on worldwide net sales subject to certain adjustments. Our obligation to pay royalties under the Safusidenib In-License Agreement will expire on a country-by-country basis upon the later of the expiration of the last valid claim of a patent licensed under the Safusidenib In-License Agreement covering safusidenib, and ten years after the first commercial sale of safusidenib in such country.

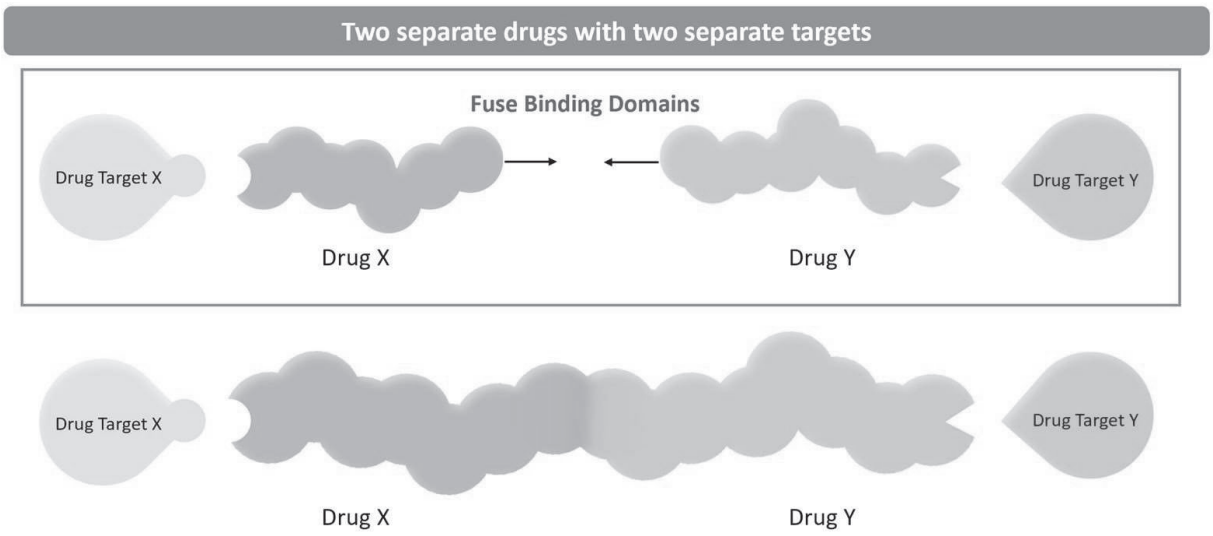
The Safusidenib In-License Agreement will continue in effect until we cease all development and commercial activity related to safusidenib. We may terminate the Safusidenib In-License Agreement on a country-by-country basis or in its entirety upon 6 months prior written notice if we have bona fide material concerns regarding the lack of efficacy of safusidenib, if all patent claims covering safusidenib are invalidated in the relevant jurisdiction, or if safusidenib is determined to infringe one or more claims of a third-party patent. Daiichi Sankyo may terminate the Safusidenib In-License Agreement if due to our insolvency or bankruptcy, or if we challenge any patents licensed under the Safusidenib In-License Agreement. Either party may terminate the agreement in the event of a material breach by the other party that remains uncured for 90 days (or, if such material breach cannot be cured within 90 days, if the other party does not commence and diligently continue actions to cure such breach during such 90 days).

We need Daiichi Sankyo's prior written consent to grant sublicenses under the rights exclusively licensed to us under the Safusidenib In-License Agreement, which Daiichi Sankyo shall not unreasonably withhold. Furthermore, we need Daiichi Sankyo's prior consent to assign our rights under the Safusidenib In-License Agreement, such consent not to be unreasonably withheld.

Overview of Our DDC Platform

The foundations of our DDCs are built by employing tissue-targeting small molecules fused to anti-cancer warheads of existing drugs with well- understood mechanisms of action. Our platform leverages our drug discovery and chemistry expertise to find the minimum target binding sites of drug X and drug Y and fuse them together, while maintaining activity. Our DDCs are designed to selectively bind to intracellular as well as surface cell membrane targets that are expressed more highly in specific target tissues and to potently deliver anti-cancer warheads to these target tissues. The figure below depicts our DDC approach.

DRUG-DRUG CONJUGATES ARE DESIGNED TO BIND TWO DIFFERENT TARGETS SIMULTANEOUSLY



Key potential benefits of our DDCs include:

- Tissue-selective targeting improves therapeutic index vs. untargeted warhead;
- Oral or IV delivery;
- Binds intracellular and cell membrane targets;
- Highly cell permeable; and
- Simpler and less expensive to manufacture than antibody-drug conjugates.

Intellectual Property

Our commercial success depends in large part on our ability to obtain and maintain patent protection in the U.S. and other countries for our investigational products, to operate without infringing valid and enforceable patents and proprietary rights of others, and to prevent others from infringing on our proprietary or intellectual property rights.

We generally seek to protect our proprietary position by pursuing patents that cover the compositions of matter, formulations, methods of use or methods of synthesis relating to our investigational products, as well as other discoveries, technologies, inventions and improvements that may be commercially important to our business. For our product candidates, we generally seek patent protection in the U.S. and in certain foreign jurisdictions.

As of December 31, 2025, taletrectinib is covered by patent families that we either own or have exclusively licensed from Daiichi Sankyo worldwide. These patent families cover the composition of matter of taletrectinib, methods of use thereof, or methods of manufacturing thereof. These patents families include issued patents as well as pending patent applications in the U.S. and certain foreign jurisdictions, and patents that have issued or may issue from these patent families are expected to expire from 2033 to 2042 (not including patent term adjustment or extension that may be available to extend the term of such patents). An application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office (the "USPTO"), requesting extension of the term of a U.S. patent covering the composition of matter of taletrectinib by five years. If the extension is granted by the USPTO, the term of the U.S. patent will be extended from 2033 to 2038.

For safusidenib, as of December 31, 2025, we have an exclusive worldwide (other than Japan) license from Daiichi Sankyo to patent families that cover the composition of matter of safusidenib, methods of use thereof, or methods of manufacturing thereof. These patents families include issued patents as well as pending patent applications in the U.S. and certain foreign jurisdictions, and patents that have issued or may issue from these patent families are expected to expire from 2035 to 2041 (not including patent term adjustment or extension that may be available to extend the term of such patents).

Because of the extensive time required for development, testing and regulatory review of an investigational product, it is possible that, before a product can be commercialized, any patent protection for such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides. In the U.S., the term of a patent covering an FDA-approved product may, in certain cases, be eligible for a patent term extension under the Hatch-Waxman Act as compensation for the loss of patent term during the FDA regulatory review process. The period of extension may be up to five years, but cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent among those eligible for an extension may be extended and the amount of available extension to any patent term extension-eligible patent depends on a variety of factors, including the date on which the patent issues and certain dates related to the regulatory review period. Possible extensions may be available in Europe and in certain other jurisdictions to extend the term of a patent that covers an approved product. While we intend to seek patent term extensions in any jurisdictions where they are available to us, there is no guarantee that the applicable authorities, including the FDA or the USPTO, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

Our trademarks are protected under the common law and/or by registration in the United States and other countries. We also rely on trade secrets to protect our technology and product candidates, especially where we do not believe patent protection is appropriate or obtainable. We seek to protect our proprietary information, in part, using confidentiality agreements with our partners, collaborators, employees and consultants.

Our commercial success may depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, obtain licenses or cease certain activities. Our failure to obtain a license to proprietary rights that we may require to develop or commercialize our future drug products may have a material adverse impact on us.

The intellectual property positions for biotechnology and pharmaceutical companies like us are generally uncertain and can involve complex legal, scientific, and factual issues. For information regarding the risks related to our intellectual property, please see "Risk Factors—Risks Related to Our Intellectual Property."

Manufacturing and Supply

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our investigational products for preclinical and clinical testing, as well as for commercial manufacture. We also rely, and expect to continue to rely, on third parties to package, label, store and distribute our investigational products, as well as for our commercial products if regulatory approval is obtained. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment and personnel while also enabling us to focus our expertise and resources on the development of our investigational products.

We obtain taletrectinib API and drug product pursuant to long-term supply agreements. We currently rely upon a single source for taletrectinib API and are working to develop a second source. For our other investigational products, we have obtained APIs and drug product from various single-source third-party CMOs. We are in the process of developing our supply chain for each of our investigational products and intend to put in place framework agreements under which CMOs will generally provide us with necessary quantities of API and drug product on a project-by-project basis based on our development needs, and which agreements will provide us with intellectual property rights necessary to conduct the business. We seek to use a different CMO for each investigational product and will consider further diversification of drug product and supply organizations as circumstances warrant. Overall, as we advance our investigational products through development, we will start by seeking multiple sources for raw materials and address other potential points of concern over time.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, development experience and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including large pharmaceutical and biotechnology companies, academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for the research, development, manufacturing and commercialization of

cancer therapies. Any investigational products that we successfully develop and commercialize will compete with new therapies that may become available in the future.

We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop small molecules and drug conjugates as treatments for cancer patients. There are many other companies that have commercialized and/or are developing such treatments for cancer including large pharmaceutical and biotechnology companies, such as AstraZeneca plc, Bristol-Myers Squibb Company ("BMS"), Eli Lilly, Merck, Novartis Pharmaceuticals Corporation ("Novartis"), Pfizer, Regeneron Pharmaceuticals, Inc. in partnership with Sanofi Genzyme ("Sanofi") and Roche.

Taletrectinib competes against approved drugs including Pfizer's Xalkori®, Roche's Rozlytrek®, and BMS's Augtyro®. Other ROS1 inhibitors currently in clinical-stage development include Nuvalent's zidesamtinib.

If approved for the treatment of mIDH1 low grade glioma, we expect that safusidenib would compete against Servier's Voranigo® (vorasidenib). Another mIDH1 currently in clinical development for mIDH1 glioma is Rigel's olutasidenib.

Many of the companies against which we are competing 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 drugs 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 early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and enrolling subjects for our clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We could see a reduction or elimination of our commercial opportunity if our competitors develop and commercialize products that are safer or 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 comparable foreign 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 investigational products, if approved, are likely to be their degree of efficacy, tolerability profile, convenience and price, the effectiveness of companion diagnostics (if required), the level of biosimilar or generic competition and the availability of reimbursement from government and other third-party payors.

Government Regulation

Government authorities in the U.S. at the federal, state and local level and in other countries regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products. The requirements and processes governing these activities vary from country to country. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

U.S. Drug Development

In the U.S., the FDA regulates drugs under the Food, Drug, and Cosmetic Act ("FDCA"). Drugs also are subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Our product candidates are considered small molecule drugs and must be approved by the FDA through the new drug application ("NDA") process before they may be legally marketed in the U.S. The process generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice ("GLP");
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board ("IRB") or ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well controlled human clinical trials in accordance with applicable IND regulations, current GCP requirements and other clinical trial-related protocols and regulations to establish substantial evidence of the safety and efficacy of the investigational product for each proposed indication;
- submission to the FDA of an NDA after completion of all pivotal trials;
- determination by the FDA within 60 days of its receipt of an NDA to accept the filing for substantive review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug will be produced to assess compliance with current Good Manufacturing Practices ("cGMP") requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA audit of the preclinical study and/or clinical trial sites that generated the data in support of the NDA filing to assess compliance with GCP;
- 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 U.S.; and
- compliance with any post-approval requirements, including the potential requirement to implement a risk evaluation and mitigation strategy ("REMS") and the potential requirement to conduct post-approval studies.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for any current and future product candidates will be granted on a timely basis, or at all.

Preclinical Studies and IND

The preclinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin.

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as in vitro and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical Trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement 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 eligibility criteria and the parameters to be used to monitor subject safety and assess efficacy. 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 in relation to anticipated benefits. The IRB must also approve 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. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

A sponsor who wishes to conduct a clinical trial outside of the U.S. 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 sponsor may submit data from the clinical trial to the FDA in support of an NDA. The FDA will generally accept a well-designed and well conducted foreign clinical trial not conducted under an IND if the clinical trial is conducted in compliance with GCP and the FDA is able to validate the data through an onsite inspection, if deemed necessary. An NDA based solely or predominantly on foreign clinical data meeting U.S. criteria for marketing approval may be approved if (1) the foreign data are applicable to the U.S. population and U.S. medical practice, (2) the studies have been performed by clinical investigators of recognized competence and (3) the FDA is able to validate the data through an onsite inspection or other appropriate means, if deemed necessary.

Clinical trials in the U.S. generally are conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, tolerability and safety of the drug.
- Phase 2 clinical trials involve studies in disease-affected patients to determine the dose and dosing schedule required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, are conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA. Sponsor is also responsible for submitting written IND safety reports, including reports of serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the drug, findings from animal or *in vitro* testing that suggest a significant risk for human subjects, and any clinically significant increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can

suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides recommendations for whether a trial may move forward at designated check-points based on access to certain data from the trial.

Concurrent with clinical trials, companies usually complete additional animal safety studies and also must develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process, as performed by the manufacturing facility, must be capable of consistently producing quality batches of our product candidates. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that our product candidates do not undergo unacceptable deterioration over their labeled shelf life.

FDA Regulation of Companion Diagnostics

A product candidate may rely upon an *in vitro* companion diagnostic for use in selecting the patients that will be more likely to respond to that therapy. If an *in vitro* diagnostic is essential to the safe and effective use of the therapeutic product, then the FDA generally will require approval or clearance of the diagnostic at the same time that the FDA approves the therapeutic product. According to FDA guidance, a companion diagnostic device used to make treatment decisions in clinical trials of a drug generally will be considered an investigational device unless it is employed for an intended use for which the device is already approved or cleared. If used to make critical treatment decisions, such as patient selection, the diagnostic device generally will be considered a significant risk device under the FDA's Investigational Device Exemption ("IDE") regulations. Thus, the sponsor of the diagnostic device will be required to comply with the IDE regulations. According to the guidance, if a diagnostic device and a drug are to be studied together to support their respective approvals, both products can be studied in the same investigational trial, if the trial meets both the requirements of the IDE regulations and the IND regulations. The guidance provides that depending on the details of the trial plan and subjects, a sponsor may seek to submit an IND alone, or both an IND and an IDE.

Pursuing FDA approval of an *in vitro* companion diagnostic would require either a pre-market notification, also called 510(k) clearance, or a pre-market approval ("PMA") for that diagnostic. The review of companion diagnostics involves coordination of review with the FDA's Center for Devices and Radiological Health. The original PMA process, including the gathering of clinical and nonclinical data and the submission to and review by the FDA, can take several years or longer. The applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness, including information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are subject to an application fee. In addition, PMAs for devices must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, the applicant must demonstrate that the diagnostic produces reliable results in the context of its intended use. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality Management System Regulation, which imposes elaborate testing, control, documentation and other quality assurance requirements.

NDA Review Process

Following completion of the clinical trials, data is analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of an NDA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. In short, the NDA is a request for approval to market the drug in the U.S. for one or more specified indications and must contain proof of safety and efficacy for a drug.

The application must 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 FDA. FDA approval of an NDA must be obtained before a drug may be legally marketed in the U.S.

Under the Prescription Drug User Fee Act ("PDUFA"), as amended, each NDA must be accompanied by a user fee. FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for each marketed human drug. 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 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. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 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 designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often extended by FDA requests for additional information or clarification.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies and/or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making the product available in the U.S. for this type of disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or in instances of drug supply issues. However, competitors may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our product candidates for seven years if a competitor

obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if a product candidate is determined to be contained within the scope of the competitor's product for the same indication. If one of our product candidates designated as an orphan drug receives marketing approval for an indication broader than that which is designated, it may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union has similar, but not identical, requirements and benefits.

Expedited Development and Review Programs

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new drugs that meet certain criteria. Specifically, new drugs are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. The sponsor can request the FDA to designate the product for fast track status any time before receiving NDA approval, but ideally no later than the pre-NDA meeting with the FDA.

Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it treats a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies.

A product may also 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 ("IMM"), which is reasonably likely to predict an effect on IMM or other 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. FDA may further require that any required confirmatory trial(s) are substantially underway at the time of accelerated approval. FDA may withdraw drug approval or require changes to the labeled indication of the drug if confirmatory post-market trials fail to verify clinical benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the drug. If the FDA concludes that a drug shown to be effective can be safely used only if distribution or use is restricted, it may require such post-marketing restrictions as it deems necessary to assure safe use of the product.

Additionally, a drug may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of breakthrough therapy designation include the same benefits as fast track designation, plus intensive guidance from the FDA to ensure an efficient drug development program. Fast track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Post-approval Requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping requirements, requirements to report adverse events and comply with promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations, known as "off-label promotion," and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such uses. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. 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 also place other conditions on approvals including the requirement for REMS, to assure the safe use of the product. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing

of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

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

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market, or product recalls;
- fines, warning letters, or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications;
- suspension or revocation of product approvals;
- product seizure or detention;
- refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and such promotion must be consistent with FDA-approved labelling. 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.

Other U.S. Regulatory Matters

Pharmaceutical manufacturers are subject to various healthcare laws, regulations, and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Our conduct, including those of our employees, as well as our business operations and relationships with third parties, including current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, as well as, sell, market, and distribute any products for which we obtain marketing approval. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Moreover, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, (collectively, the "Affordable Care Act") provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act.
- The federal false claims laws, including the civil False Claims Act that can be enforced by private citizens through civil whistleblower or *qui tam* actions, and civil monetary penalties law prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government.

- The federal Health Insurance Portability and Accountability Act ("HIPAA") prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their implementing regulations also impose obligations on covered entities such as health insurance plans, healthcare clearinghouses, and certain healthcare providers and their respective business associates and covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.
- The federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to the Centers for Medicare & Medicaid Services ("CMS") information regarding certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members.
- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, state laws that require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and require the registration of their sales representatives, state laws that require biotechnology companies to report information on the pricing of certain drug products, and state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws. In addition, the distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act as well as other applicable consumer safety requirements.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to comply can result in significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, injunctions, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts.

U.S. Patent-Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of any future product candidates, some of our U.S. patents, or U.S. patent applications, if issued, may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent-term restoration period is generally one-half the time between the effective date of an IND or the issue date of the patent, whichever is later, and the submission date of an NDA plus the time between the submission date of an NDA or the issue date of the patent, whichever is later, and the approval of that application,

except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application ("ANDA"), or a 505(b)(2) NDA submitted by another company for a generic version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness or generate such data themselves.

European Union Drug Development

In the European Union, medicinal products are subject to extensive regulatory requirements. As in the United States, medicinal products can be marketed only if a marketing authorization from the competent regulatory authorities has been obtained.

The various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. In the EU, clinical trials are governed by the Clinical Trials Regulation (EU) No 536/2014, or CTR, which entered into application on January 31, 2022 repealing and replacing the former Clinical Trials Directive 2001/20, or CTD, and related national implementing legislation of EU Member States.

The CTR is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increasing their transparency. Specifically, the Regulation, which is directly applicable in all EU Member States, introduces a streamlined application procedure through a single-entry point, the "EU portal", the Clinical Trials Information System; a single set of documents to be prepared and submitted for the application; as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reference Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU Member States. This assessment is then submitted to the competent authorities of all concerned Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and Ethics Committees in each concerned EU Member State. Individual EU Member States retain the power to authorize the conduct of clinical trials on their territory. The CTR foresaw a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans.

European Union Drug Review and Approval

In the European Economic Area ("EEA"), which comprises the 27 Member States of the European Union and three European Free Trade Association States (Norway, Iceland and Liechtenstein), medicinal products can only be commercialized after obtaining a Marketing Authorization ("MA").

To obtain an MA for a product in the EEA, an applicant must submit a MAA either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in the EEA countries

(decentralized procedure, national procedure or mutual recognition procedure). An MA may be granted only to an applicant established in the EEA.

The centralized procedure provides for the grant of a single MA by the European Commission that is valid for all EEA countries. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced therapy medicinal products, and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, authorization through the centralized procedure is optional on related approval.

Under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use, or CHMP, conducts the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA.

Under the centralized procedure in the EEA, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product targeting an unmet medical need is expected to be of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (excluding clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Unlike the centralized authorization procedure, the decentralized MA procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EEA country in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EEA countries who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the Heads of Medicines Agencies' Coordination Group for Mutual Recognition and Decentralised Procedures – Human, or CMDh, for review. The subsequent decision of the European Commission is binding on all EEA countries.

The mutual recognition procedure allows companies that have a medicinal product already authorized in one EEA country to apply for this authorization to be recognized by the competent authorities in other EEA countries. Like the decentralized procedure, the mutual recognition procedure is based on the acceptance by the competent authorities of the EEA countries of the MA of a medicinal product by the competent authorities of other EEA countries. The holder of a national MA may submit an application to the competent authority of an EEA country requesting that this authority recognize the MA delivered by the competent authority of another EEA country.

An MA has, in principle, an initial validity of five years. The MA 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 EEA country in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the eCTD (Common Technical Document) providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission or the competent authorities of the EEA countries may decide on justified grounds relating to pharmacovigilance, to proceed with one further five-year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for a centralized MA) or on the market of the authorizing EEA country within three years after authorization ceases to be valid (the so-called sunset clause).

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines, or PRIME, scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet

medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicinal product will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

Accelerated and Alternative Marketing Authorization Mechanisms

Importantly, a dedicated contact and rapporteur from the EMA's Committee for Human Medicinal Products, or CHMP, or Committee for Advanced Therapies, are appointed early in the PRIME scheme facilitating increased understanding of the product at EMA's Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies. Where, during the course of development, a medicine no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn.

A "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional MA for a medicinal product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance of the medicinal product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicinal product fulfils an unmet medical need; and (iv) the benefit of the immediate availability to patients of the medicinal product is greater than the risk inherent in the fact that additional data are still required. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a traditional MA. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the MA will cease to be renewed.

An MA may also be granted "under exceptional circumstances" where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the MA will be withdrawn if the risk-benefit ratio is no longer favorable.

Pediatric Development

In the EU, Regulation (EC) No 1901/2006 provides that all MAAs for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan (PIP), agreed with the EMA's Pediatric Committee (PDCO). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU Member States and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate, or SPC, if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

Data and Market Exclusivity

The EU provides opportunities for data and market exclusivity related to MAs. Upon receiving an MA, innovative medicinal products are generally entitled to receive eight years of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial MA of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the MA 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. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for MA. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

Orphan Designation

In the EU, Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000 provides that a medicinal product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that: (i) the product is intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions; (ii) either (a) such conditions affect not more than 5 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 developing the medicinal product; and (iii) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the EU, or even if such method exists, the product will be of significant benefit to those affected by that condition.

Regulation (EC) No 847/2000 sets out further provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product. An application for the designation of a medicinal product as an orphan medicinal product must be submitted at any stage of development of the medicinal product but before filing of an MAA. An MA for an orphan medicinal product may only include indications designated as orphan. For non-orphan indications treated with the same active pharmaceutical ingredient, a separate marketing authorization has to be sought.

Orphan medicinal product designation entitles an applicant to incentives such fee reductions or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. Upon grant of a marketing authorization, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another marketing authorization application or accept an application to extend for a similar product and the European Commission cannot grant a marketing authorization for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product designation, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, an MA may be granted to a similar medicinal product with the same orphan indication during the 10 year period if: (i) if the applicant consents to a second original orphan medicinal product application, (ii) if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) if the second applicant can establish that its product, although similar, is safer, more

effective or otherwise clinically superior to the original orphan medicinal product. A company may voluntarily remove a product from the register of orphan products.

Post-Authorization Requirements

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EU Member States. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports (PSURs).

All new MAAs must include a risk management plan (RMP), describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk- minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

Other EU Compliance Requirements

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products are established in EU law. However, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics (SmPC), which may require approval by the competent national authorities in connection with an MA. The SmPC is the document that provides information to physicians and other healthcare professionals concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU.

Much like the Anti-Kickback Statute prohibition in the United States, described above, the provision of benefits or advantages to physicians and other health care professionals to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. Interactions between pharmaceutical companies and health care professionals are governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. Infringement of related laws could result in substantial fines and imprisonment.

Payments made to physicians and other health care professionals in certain EU Member States must be publicly disclosed. Moreover, agreements with health care professionals may require prior notification or approval by the health care professional's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Regulation of Companion Diagnostics in the EU

In the EEA, companion diagnostics are deemed to be *in vitro* diagnostic medical devices (IVDs), and are governed by Regulation 2017/746 (IVDR), which entered into application on May 26, 2022, repealing and replacing Directive 98/79/EC.

The IVDR defines a companion diagnostic as a device which is essential for the safe and effective use of a corresponding medicinal product to: (a) identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or (b) identify, before and/or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product.

The IVDR and its associated guidance documents and harmonized standards govern, among other things, device design and development, preclinical and clinical or performance testing, premarket conformity assessment, registration and listing, manufacturing, labeling, storage, claims, sales and distribution, export and import and post-market surveillance, vigilance, and market surveillance. IVDs, including companion diagnostics, must conform with the general safety and performance requirements (GSPRs), of the IVDR. Compliance with these requirements is a prerequisite to be able to affix the CE mark to devices, without which they cannot be marketed or sold in the EEA. To demonstrate compliance with the GSPR laid down in Annex I to the IVDR, and obtain the right to affix the CE mark, IVD manufacturers must conduct a conformity assessment procedure, which varies according to the type of IVD and its classification. Apart from low risk IVDs (Class A which are not sterile), in relation to which the manufacturer may issue an EU Declaration of Conformity based on a self-assessment of the conformity of its products with the GSPRs, a conformity assessment procedure requires the intervention of a Notified Body, which is an organization designated by a Competent Authority of an EEA country to conduct conformity assessments. Depending on the relevant conformity assessment procedure, the Notified Body audits and examines the technical documentation and the quality system for the manufacture, design and final inspection of the medical devices. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the GSPRs. This Certificate and the related conformity assessment process entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

Companion diagnostics must undergo a conformity assessment by a Notified Body. If the related medicinal product has, or is in the process of, being authorized through the centralized procedure for the authorization of medicinal products, the notified body will, before it can issue a CE Certificate of Conformity, be required to seek a scientific opinion from the EMA on the suitability of the companion diagnostic for use in relation to the medicinal product concerned. For medicinal products that have or are in the process of authorization through any other route provided in EU legislation, the Notified Body must seek the opinion of the national competent authority of an EU Member State.

Coverage and Reimbursement

Sales of our products and our product candidates, if approved, will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the U.S., for example, principal decisions about reimbursement for new products are typically made by CMS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis.

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. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost effectiveness of our products. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Additionally, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are

not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan likely will be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private third-party payors often follow Medicare coverage policy and payment limitations in setting their own payment rates.

In addition, in case a drug product needs companion diagnostics, then companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

Further, recently, in the U.S. there has been heightened governmental scrutiny of the manner in which drug manufacturers set prices for their marketed products. Pricing pressures can arise from rules and practices of managed care organizations, judicial decisions and governmental laws and regulations related to Medicare, Medicaid, healthcare reform, pharmaceutical reimbursement policies and pricing in general. For example, the U.S. Department of Health and Human Services ("HHS") imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. In addition, HHS has been empowered to negotiate the price of certain single-source drugs that have been on the market for at least 7 years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to 20 products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize IBTROZI or any of our product candidates that we develop.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, in the EEA, some countries may restrict the range of products for which their national health insurance systems provide reimbursement. Other countries may control the prices of medicinal products for human use or allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Such pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. Political, economic and regulatory developments may further complicate pricing negotiations. In addition, other countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies (so called Health Technology Assessments ("HTAs")) in order to obtain reimbursement or pricing approval. HTAs of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in EEA countries, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. In December 2021, Regulation No 2021/2282 on HTA, was adopted in the EU. This Regulation, which entered into application on January 12, 2025 and has a phased implementation, is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation initially applies to new active substances for oncology and ATMPs. It will be expanded to orphan medicinal products in January 2028, and to all centrally authorized medicinal products as of 2030. Select high-risk medical devices also came into scope in 2026. The Regulation permits EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. In addition, some EEA countries may approve a specific price for a product, or they may instead adopt a system of direct

or indirect controls on the profitability of the company placing the product on the market. Other EEA countries allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions.

There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

Healthcare Reform

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, the Affordable Care Act substantially changed the way healthcare is financed by both the government and private insurers and continues to significantly impact the U.S. pharmaceutical industry.

Since its enactment, there have been executive, judicial and Congressional challenges and amendments to certain aspects of the Affordable Care Act. For example, on July 4, 2025, the One Big Beautiful Bill Act ("OBBBA"), was signed into law, which narrowed access to Affordable Care Act marketplace exchange enrollment and declined to extend the Affordable Care Act enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired Affordable Care Act subsidies. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and other litigation, and the healthcare reform measures of the second Trump administration will impact the Affordable Care Act.

Other legislative changes have been proposed and adopted in the U.S. since the Affordable Care Act was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect until 2032, unless additional congressional action is taken. These and other future healthcare reform measures may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

Additionally, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in reform measures designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with pharmaceutical companies that require the drug manufacturers to offer, through a direct-to-consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024,

in Loper Bright Enterprises v. Raimondo, the U.S. Supreme Court greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs. We are unable to predict the future course of federal or state healthcare legislation in the U.S. directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. These and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations.

Facilities

Our principal executive offices are located in New York, New York, where we lease approximately 7,900 square feet of office space under a lease that terminates in 2027, with an option for us to extend the lease for an additional five years which is not reasonably assured of exercise, and in San Francisco, where we lease approximately 19,418 square feet of office space that terminates in 2029. We also occupy office space located in Burlington, Massachusetts, where we lease approximately 2,235 square feet of office space under a lease that terminates in 2027, as well as a total of approximately 1,799 square meters of office space in the People's Republic of China, in the cities of Beijing, Guangzhou, Hangzhou and Shanghai, under leases that terminate in 2026 through 2029.

Human Capital

Employees

As of December 31, 2025, we had 298 full-time employees, 58 of whom hold Ph.Ds, M.Ds or Pharm.Ds. Of our total workforce, 147 employees are engaged in research and development, and 151 employees in selling, general and administrative. Our workforce also includes 67 independent contractors. We have no collective bargaining agreements with our employees, and we have not experienced any work stoppages nor are we aware of any employment circumstances that are likely to disrupt work at any of our facilities. We consider our relationship with our employees to be strong.

Human Capital Management

We recognize that attracting, motivating and retaining talent at all levels is vital to our continued success. Our employees are a significant asset, and we aim to create an environment that is equitable, inclusive and representative in which our employees can grow and advance their careers, with the overall goal of developing, expanding and retaining our workforce to support our current pipeline and future business goals. By focusing on employee retention and engagement, we also improve our ability to support our clinical-stage platform, business and operations, and also protect the long-term interests of our securityholders. Our success also depends on our ability to attract, engage and retain a diverse group of employees. Our efforts to recruit and retain a diverse and passionate workforce include providing competitive compensation and benefits packages and ensuring we listen to our employees.

We value agility, passion and teamwork, and are building an engagement environment where our employees can thrive and one that inspires exceptional contributions and professional and personal development in order to achieve our mission to significantly change the practice of oncology. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives. We are committed to providing a competitive and comprehensive benefits package to our employees. Our benefits package provides a balance of protection along with the flexibility to meet the individual health and wellness needs of our employees.

Diversity and Inclusion

Diversity and inclusion are priorities for us. We believe that a rich culture of inclusion and diversity enables us to create, develop and fully leverage the strengths of our workforce. Our workforce comprises approximately 58% female employees and approximately 34% racial/ethnic minority employees.

Legal Proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business.

On July 30, 2025, Tim Patterson filed a derivative complaint (Tim Patterson, derivatively on behalf of Nuvation Bio, Inc. v. David Hung, et al. Index No. 654535/2025) (the "Action") in the Supreme Court of the State of New York for the County of New York on behalf of Nuvation Bio against our seven current directors and one former director (the "Individual Defendants"). The Action asserts claims against the Individual Defendants for allegedly breaching their fiduciary duties to us by awarding our directors excessive compensation between 2021 and 2024 and seeks restitution from the Individual Defendants, changes to our director compensation policies and practices, and attorneys' fees and other costs of suit. On November 12, 2025, the plaintiff voluntarily discontinued the Action without prejudice.

Available Information

We were incorporated in Delaware in April 2020 as a blank check company under the name Panacea Acquisition Corp. On February 10, 2021, Nuvation Bio and Panacea consummated the transactions contemplated under the Merger Agreement, following the approval at a special meeting of our stockholders. In connection with the closing of the Merger, we changed our name to Nuvation Bio Inc.

We file electronically with the U.S. Securities and Exchange Commission, or SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended. We make available on our website at www.nuvationbio.com, free of charge, copies of these reports as soon as reasonably practicable after filing these reports with, or furnishing them to, the SEC.

Item 1A. Risk Factors.

Our business and investing in our securities involve significant risks, some of which are described below. Before you make a decision to buy our securities, in addition to the risks and uncertainties discussed in the section titled "Cautionary Information Regarding Forward-Looking Statements," you should carefully consider the risks and uncertainties described below together with all of the other information contained in this Annual Report on Form 10-K, including our financial statements and related notes and in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or developments described in the following risk factors and the risks described elsewhere in this report could harm our business, financial condition, results of operations, cash flows, the trading price of our common stock and our growth prospects. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. This report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described in the following risk factors and the risks described elsewhere in this report.

Risks Related to Commercialization of IBTROZI

Our near-term prospects are significantly dependent on the commercialization of IBTROZI. If we are unable to successfully commercialize IBTROZI, our ability to generate meaningful revenue or achieve profitability will be materially and adversely affected.

In June 2025, we received FDA approval to commercialize IBTROZI in the U.S. for the treatment of adult patients with locally advanced or metastatic ROS1+ NSCLC, and we initiated a commercial launch of IBTROZI in the U.S. in that indication. IBTROZI is our only product approved for marketing by the FDA, and our ability to generate revenue from product sales and achieve profitability is mostly dependent on our ability to successfully commercialize IBTROZI in the U.S. We may not be able to successfully commercialize IBTROZI for a number of reasons, including:

- we may not be able to establish or demonstrate in the medical community the safety and efficacy of IBTROZI and its potential advantages over existing treatments;
- physicians may be reluctant to prescribe IBTROZI until longer-term efficacy and safety data exists;
- the length of time that patients who are prescribed IBTROZI remain on treatment may be shorter than we anticipate;
- our limited historical experience in marketing, selling and distributing IBTROZI;
- our ability to access or reach prescribers;
- the reimbursement and coverage policies of government and private payors such as Medicare, Medicaid, insurance companies, health maintenance organizations and other plan administrators;
- our ability to influence testing and appropriate patient identification processes within accounts, especially in the community setting where testing and patient identification rates are lower than in the academic setting;
- the relative price of IBTROZI as compared to alternative treatment options;
- the relatively low incidence and prevalence of patients in IBTROZI's approved indication, including the reliability of our market and sales estimates;
- future competitive or other market factors that may adversely affect the commercial potential of IBTROZI;
- we may not be able to obtain and maintain regulatory approvals for taletrectinib in any other jurisdictions or for any other indications;
- changed or increased regulatory restrictions;
- changes to the label for IBTROZI that could restrict how we market and sell IBTROZI, including adverse events observed in ongoing and future studies of taletrectinib such as TRUST-I and TRUST-II;
- the capabilities of third-party manufacturers may adversely affect the success of our commercialization of IBTROZI; and
- we may not be able to maintain adequate commercial supplies of IBTROZI to meet demand.

Moreover, successful commercialization of IBTROZI may not generate sufficient revenue from product sales, and we may not become profitable in the near term, or at all. If we are unable to successfully commercialize IBTROZI, our ability to generate meaningful revenue from product sales and achieve profitability will be materially and adversely affected, which in turn would severely and adversely affect our financial results, business and business prospects.

We have limited experience as a commercial company and our sales, marketing, and distribution of IBTROZI may be unsuccessful or less successful than anticipated.

As a company, we have limited experience in selling and marketing or commercializing an approved drug product in the U.S., and no such experience outside of the U.S. The success of our U.S. commercialization efforts is subject to, among other things, managing our internal sales, marketing, and distribution capabilities and our ability to navigate the significant expenses and risks involved with the management of such capabilities. For example, our commercial launch of IBTROZI in the U.S. may not continue as planned or anticipated, which may require us to, among others, adjust or amend our commercialization plan and incur significant expenses. If we are unsuccessful in accomplishing our objectives or if our commercialization efforts do not continue as planned, we may not be able to successfully commercialize IBTROZI, we may require significant additional capital and financial resources, we may not become profitable, and we may not be able to compete against more established companies in our industry, any of which would severely and adversely affect our financial results, business and business prospects.

Given our limited experience in marketing and selling IBTROZI in the U.S., our initial estimate of the size of the required sales force may be materially more or less than the size of the sales force actually required to effectively commercialize IBTROZI. As such, we may be required to hire substantially more sales representatives and medical

support liaisons to adequately support the commercialization of IBTROZI, or we may incur excess costs as a result of hiring more sales representatives and medical support liaisons than necessary.

If the market opportunities for IBTROZI are smaller than we believe, our revenue may be adversely affected, and our business may suffer.

We are commercializing IBTROZI in advanced ROS1+ NSCLC, and the addressable patient population in advanced ROS1+ NSCLC is based on our estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations and market research, may prove to be incorrect. Further, new information from us or others may change the estimated incidence or prevalence of patients with advanced ROS1+ NSCLC. We may be unable to successfully identify patients and achieve a significant market share in IBTROZI's approved indication.

Our market opportunity may also be limited by the pricing, reimbursement and access we are able to achieve for IBTROZI, the quality and expiration of our intellectual property rights and regulatory exclusivity, duration of IBTROZI treatment in advanced ROS1+ NSCLC and future competitor treatments that enter the market. If any of our estimates prove to be inaccurate, the market opportunities for IBTROZI that we or any potential future collaborative partners develop could be significantly diminished, which would have a material adverse impact on our business and business prospects, and would adversely affect our ability to achieve profitability.

IBTROZI may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If IBTROZI does not achieve an adequate level of acceptance, we may not generate significant product revenues and we may never become profitable. For example, current approved immunotherapies, and other cancer treatments like chemotherapy and radiation therapy, are well established in the medical community, and doctors may continue to rely on these therapies. The degree of market acceptance of IBTROZI will depend on a number of factors, including:

- the ability of IBTROZI to treat advanced ROS1+ NSCLC, as compared with other available drugs, treatments or therapies;
- the prevalence and severity of any adverse side effects associated with our product candidates;
- the label and promotional claims allowed by the FDA for IBTROZI and any limitations or warnings about the prevalence or severity of any side effects;
- limitations or warnings contained in the labeling approved for our product candidates by the FDA or comparable foreign regulatory authorities;
- availability of alternative treatments;
- the size of the target patient population, and the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the effectiveness of sales, marketing and distribution support for IBTROZI;
- the ability of the third-party distributors and specialty pharmacies we contract with to process prescriptions and dispense IBTROZI and the processes required to place orders with such distributors and specialty pharmacies;
- the pricing and cost effectiveness of IBTROZI, both in absolute terms and relative to alternative treatments;
- the extent to which IBTROZI is approved for inclusion on formularies in hospitals and managed care organizations;
- our ability to obtain sufficient third-party coverage and adequate reimbursement; and
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors, including governmental authorities.

The successful commercialization of IBTROZI and our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels and pricing policies. Failure to obtain or maintain adequate coverage and reimbursement for IBTROZI or our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid in the U.S., comparable foreign healthcare programs, private health insurers and other third-party payors are essential for most patients to be able to afford products such as IBTROZI. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize IBTROZI and our product candidates, if approved, and, if desired, attract collaboration partners to invest in the development of our product candidates. Coverage under certain government programs, such as Medicare, Medicaid, the 340B drug pricing program and TRICARE, or comparable foreign healthcare programs, may not be available for IBTROZI and certain of our product candidates, if approved. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the U.S., European Union Member States, China or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates and other therapies as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing drugs may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the U.S., third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Taletrectinib is also approved in China for the treatment of advanced ROS1+ NSCLC and sold under the brand name DOVBLREON. In China, the Ministry of Human Resources and Social Security of China or provincial or local human resources and social security authorities, together with other government authorities, review the inclusion or removal of drugs from China's National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance, or the National Reimbursement Drug List ("NRDL"), or provincial or local medical insurance catalogues for the National Medical Insurance Program regularly, and the tier under which a drug will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs. There can be no assurance that taletrectinib or any of our product candidates, if approved, will be included in the NRDL. Products included in the NRDL have been typically generic and essential drugs. Innovative drugs similar to taletrectinib have historically been more limited on their inclusion in the NRDL due to the affordability of the government's Basic Medical Insurance, although this has been changing in recent years. Obtaining and maintaining reimbursement status is time-consuming and costly. No uniform policy for coverage and reimbursement for products exists among third-party payors in the U.S. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Moreover, increasing efforts by governmental and third-party payors in the U.S. 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. For example, HHS imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. In addition, HHS has been empowered to negotiate the price of certain single-source drugs that have been on the market for at least 7 years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to 20 products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize IBTROZI and our product candidates that we develop, which could have an adverse effect on our operating results and our overall financial condition.

We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care may adversely affect:

- the demand for any products for which we may 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 revenues and achieve or maintain profitability; and
- the amount of taxes that we are required to pay.

In addition, in case a drug product needs companion diagnostics, then companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for the pharmaceutical or biological product. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

We rely on a select network of third-party distributors, specialty pharmacies and other vendors to distribute IBTROZI in the U.S., and any failure by such distributors, specialty pharmacies and vendors could adversely affect our revenues, financial condition, or results of operations.

We rely on a select network of third-party distributors, specialty pharmacies and other vendors to distribute IBTROZI in the U.S., and the financial failure of any of these parties could adversely affect our revenues, financial condition or results of operations. We rely on such distributors and specialty pharmacies to effectively distribute IBTROZI in a timely manner, provide certain patient support services, manage prescription intake, collect accurate patient and inventory data and collect payments from payors. While we have entered into agreements with each of these parties, they may not perform as agreed, our strategic priorities may change or they may terminate their agreements with us. Further, an inability by our distributors or specialty pharmacies to meet our patients' needs may lead to reputational harm or patient loss. In the event that such network fails to properly meet our or our patients' needs, we may need to partner with other distributors, specialty pharmacies or vendors to replace or supplement our current network and there is no guarantee that we will be able to do so on commercially reasonable terms or at all.

If competitors develop products, product candidates or technologies that are superior to or more cost-effective than IBTROZI, it would significantly impact the development and commercial viability of IBTROZI, which would severely and adversely affect our financial results, business and business prospects, and the future of IBTROZI, and might cause us to cease operations.

The pharmaceutical and biotechnology industries are characterized by intense and dynamic competition with rapidly advancing technologies and a strong emphasis on proprietary products. IBTROZI competes with other products and therapies that currently exist, are being developed or will in the future be developed, some of which we may not currently be aware of.

Competitors may develop more commercially desirable or affordable products than IBTROZI. Competitors have developed, or are in the process of developing, technologies that are, or in the future may be, competitive to IBTROZI. Some of these products may have an entirely different approach or means of accomplishing therapeutic effects similar or superior to those that may be demonstrated by IBTROZI. Competitors may develop products that are safer, more effective, or less costly than IBTROZI, or more convenient to administer to patients and, therefore, present a serious competitive threat to IBTROZI. In addition, competitors may price their products below what we may determine to be an acceptable price for IBTROZI, may receive better third-party payor coverage and/or reimbursement, or may be more cost-effective than IBTROZI. Such competitive products or activities by competitors may render IBTROZI obsolete, which may cause us to cease any further development or future commercialization of IBTROZI, which would severely and adversely affect our financial results, business and business prospects, and the future of IBTROZI.

If we are unable to maintain our agreements with third parties to sell and market taletrectinib in jurisdictions outside of the U.S. or our partnered territories, we will be unable to successfully commercialize taletrectinib if and when it is approved in such jurisdictions.

We have out-licensed commercial rights to taletrectinib to Innovent in mainland China, Hong Kong, Macau and Taiwan; to NK in Japan; and to Eisai in Europe and other territories. In the future, we may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for, taletrectinib in territories outside of the U.S. and territories subject to existing partnerships, or for our other product candidates if and when they are approved.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the benefits of prescribing any future product candidates;
- the lack of complementary products offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues to us are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties and we cannot assure you that such third parties will establish adequate sales and distribution capabilities or devote the necessary resources and attention to sell and market our product candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Failure by us to maintain a manufacturing supply chain to appropriately and adequately supply IBTROZI for commercial and future clinical uses would adversely affect our ability to commercialize IBTROZI and/or result in a further delay in or cessation of clinical trials, and our business and business prospects could be severely harmed.

The manufacture of IBTROZI must comply with applicable regulatory standards for commercial uses and current and potential future clinical trials. The process of manufacturing IBTROZI is complex and subject to several risks, including:

- the ability to consistently manufacture sufficient yields with acceptable quality control and quality assurance to meet market demand for our commercialization of IBTROZI, as well as the needs for continuing clinical trials;
- our ability to maintain existing commercial supply agreements and to establish additional or alternative supply agreements if necessary, including our ability to successfully transfer manufacturing technology and attain regulatory approval at any such additional or alternative suppliers;
- reliance on third-party manufacturers and suppliers, whose efforts we do not control;
- supply chain issues, including the timely availability of product raw materials, drug substance, and drug product and other supplies, any of which may be impacted by a number of factors, including the effects of macroeconomic or other global conditions;
- shortage of qualified personnel at any of our third-party suppliers; and
- regulatory acceptance and continued compliance with regulatory requirements, which vary in each country.

As a result of these and other risks, we may be unable to maintain a manufacturing infrastructure and supply chain capable of providing IBTROZI for clinical and commercial use, which would delay or adversely affect our IBTROZI commercialization efforts; result in lost sales; delay or result in a cessation of our current or potential future clinical trials; delay or preclude potential future regulatory approvals of IBTROZI in other jurisdictions or indications; and could cause financial and reputational harm.

Risks Related to the Regulatory Approval of IBTROZI

We may be unable to maintain regulatory approval for IBTROZI in the U.S. or other jurisdictions, which would severely and adversely affect our business and business prospects.

IBTROZI has been approved in the U.S., Japan and in China (sold under the brand name DOVBLREON) for the treatment of advanced ROS1+ NSCLC. Approved products are subject to extensive and ongoing regulatory requirements for manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, sampling and record-keeping. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current Good Manufacturing Practice ("cGMP"), regulations and Good Clinical Practice ("GCP"), for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products. In addition, 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 testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory authorities as reflected in the product's approved labeling. If we receive marketing approval for any future product candidates we may develop, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. However, if we are found to have promoted such off-label uses, we may become subject to significant liability.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, the U.S. Supreme Court's June 2024 decision in Loper Bright Enterprises v. Raimondo (the "Loper Bright decision") overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Bright decision could result in additional legal challenges to regulations and decisions issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the Loper Bright decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. Moreover, if there are changes in the application of legislation or regulatory policies, or if problems are discovered with a product or our manufacture

of a product, or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include:

- issuing warnings or untitled letters;
- seeking an injunction or imposing civil or criminal penalties or monetary fines;
- suspension or imposition of restrictions on operations, including product manufacturing;
- seizure or detention of products, refusal to permit the import or export of products or request that we initiate a product recall;
- suspension, variation or withdrawal of our marketing authorizations;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to applications submitted by us; or
- requiring us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization.

If any of these events occur, our ability to sell our approved products may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could harm our business, financial condition, results of operations and prospects.

Our regulatory approvals for taletrectinib in the U.S. and China for advanced ROS1+ NSCLC are subject to certain post-marketing requirements and/or commitments, and we may be subject to penalties or product withdrawal if we fail to comply with these regulatory requirements and commitments or if we experience unanticipated problems with taletrectinib.

Our regulatory approval for IBTROZI in the U.S. in advanced ROS1+ NSCLC is subject to post-marketing requirements and commitments, including:

- a pediatric study;
- a multicenter cohort in TRUST-II to further characterize the PK and safety of taletrectinib 400 mg daily taken with standard meals, in patients with advanced or metastatic ROS1+ NSCLC;
- a hepatic impairment clinical trial to determine the PK and safety of taletrectinib in patients with moderate and severe hepatic impairment;
- clinical drug interaction studies to evaluate the effect of taletrectinib on pharmacokinetics of certain sensitive CYP and transport substrates;
- a clinical trial to evaluate and inform on the exposure of taletrectinib when taken with H2-receptor antagonists;
- complete TRUST-I and TRUST-II studies, including a minimum of 18 months of response and follow-up for all pivotal patients; and
- an analytical and clinical validation study to support the development of a companion diagnostic.

Our regulatory approval for taletrectinib in China (sold under the brand name DOVBLERON) in advanced ROS1+ NSCLC is subject to a post-marketing requirement to establish the clinical benefit of the drug in a confirmatory clinical trial.

Failure to comply with these post-marketing requirements and commitments or any other regulatory requirements, or later discovery of previously unknown problems with taletrectinib, or our manufacturers, or manufacturing processes for taletrectinib, may result in actions that could severely and adversely affect our business, such as:

- restrictions on taletrectinib manufacturing, distribution or use;
- restrictions on labeling or marketing;

- additional post-marketing requirements or commitments; warning letters, withdrawal of taletrectinib from the market;
- product recalls;
- suspension or termination of ongoing clinical trials of taletrectinib in other indications;
- significant civil, criminal and administrative penalties, including fines, restitutions or disgorgement of profits or revenues;
- refusal to permit the import or export of taletrectinib;
- product seizure or detentions; injunctions or the imposition of civil or criminal penalties; and
- adverse publicity.

If we or others later discover that IBTROZI or any of our future approved product candidates is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market such approved drug could be compromised.

- Clinical trials of our product candidates are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If we, or others, discover that IBTROZI or any of our future approved product candidates are less effective than previously believed, or cause undesirable side effects, a number of potentially significant negative consequences could result, including:
- withdrawal, variation, suspension or limitation by regulatory authorities of approvals of such product;
- product candidate is approved under 21 CFR 314 (Subpart H, accelerated approval) or we receive a conditional marketing authorization but required confirmatory trials may fail to verify clinical benefit or we may fail to fulfill requirements of the conditional marketing authorization;
- seizure of the product by regulatory authorities;
- recall of the product;
- restrictions on the marketing of the product or the manufacturing process for any component thereof;
- requirement by regulatory authorities of additional warnings on the label, such as a “black box” warning or contraindication;
- requirements that we implement a REMS, or comparable foreign strategies, or create a medication guide outlining the risks of such side effects for distribution to patients;
- commitment to expensive additional safety studies prior to approval or post-marketing studies required by regulatory authorities of such product;
- adverse impact on the product’s competitiveness;
- initiation of regulatory investigations and government enforcement actions;
- initiation of legal action against us to hold us liable for harm caused to patients; and
- harm to our reputation and resulting harm to physician or patient acceptance of our products.

Any of these events could prevent us from achieving or maintaining market acceptance of IBTROZI or any of our future approved product candidates, and could harm our business, financial condition, results of operations and prospects.

Risks Related to Our Financial Position and Need for Additional Capital

We are unable to predict if or when we will generate significant revenue or profits.

We are incurring and have incurred net losses every year since our operations began in 2018. Losses have resulted principally from costs incurred in connection with our research and development activities, and from general and administrative costs associated with our operations. Although we have recently begun to commercialize IBTROZI, our revenue and profit potential is unproven and our very limited operating history as a commercial company makes our future operating results difficult to predict. If we do not generate significant revenue from commercial sales of IBTROZI, or if we experience unforeseen events or choose to make other investments in our business, we may continue to experience negative cash flow as we fund our operations and clinical development activities and research programs, and continue with the commercialization of IBTROZI. We will need to generate significant revenues to achieve consistent future profitability, and we may never achieve consistent future profitability. Even if we do become profitable in the future, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to achieve consistent future profitability could negatively impact the market price of our common stock and our ability to sustain operations.

Our clinical-stage product candidates as well as our other pipeline assets will require significant further investment and regulatory approvals prior to commercialization. Our product candidates will require additional clinical development, management of clinical, preclinical and manufacturing activities, obtaining regulatory approval, obtaining manufacturing supply, build out of additional commercial infrastructure, substantial investment and significant marketing efforts, before we generate any revenues from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our clinical-stage product candidates, including safusidenib, which is in a Phase 3 study. We anticipate incurring significant costs associated with launching and commercializing our current and future product candidates, including as a result of payment obligations under the Taletrectinib In-License Agreement, the Safusidenib In-License Agreement, our revenue interest financing agreement with Sagard Healthcare Partners (Delaware) II LP (the "RIF Agreement"), and our credit agreement and guaranty with Sagard Holdings Manager LP (the "Loan Agreement"). Furthermore, if the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products. Our revenues will also depend, in part, upon our current collaborators' and future collaborators' ability to obtain regulatory approval and successfully commercialize our product candidates in their respective territories. We would continue to bear the risk that the FDA or similar foreign regulatory authorities such as the European Commission, the U.K. Medicines & Healthcare Products Regulatory Agency ("MHRA") or the National Medical Product Administration of China ("NMPA"), could revoke approval, or that safety, efficacy, manufacturing or supply issues could arise that negatively impact product sales.

Even if we generate sufficient revenue to achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease our value and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in value also could cause you to lose all or part of your investment.

We will need substantial funding to pursue our business objectives. If we are unable to receive significant revenues from the sales of our product or if we are unable to raise capital if and when needed or on favorable terms, we could be forced to delay, reduce or terminate our product development, other operations or commercialization efforts.

Successful drug development and commercialization requires significant amounts of capital. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our ongoing and planned commercialization efforts for IBTROZI, and our development and regulatory approval efforts with respect to our current and future product candidates. Our expenses could increase beyond our current expectations if the FDA, or comparable foreign regulatory authorities, require us to perform clinical trials and other studies in addition to those that we currently anticipate. 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 on attractive terms, we will be forced to delay, reduce or terminate our research and development programs or commercialization efforts.

As of December 31, 2025, we had $529.2 million in cash and investments, and an accumulated deficit of $1,115.4 million. Based upon our current operating plan, we believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operations for at least the next 12 months. This estimate is based

on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in and progress of our development activities and changes in regulation. Our future capital requirements will depend on many factors, including:

- the level of demand for IBTROZI;
- the extent to which coverage and reimbursement for IBTROZI is available from government and health administration authorities, private health insurers, managed care programs and other third-party payors;
- changes in the amount of deductions from gross sales, including government-mandated rebates, chargebacks and discounts that can vary because of changes to the government discount percentage, including increases in the government discount percentage resulting from price increases we may take in the future, or due to different levels of utilization by entities entitled to government rebates and discounts and changes in patient demographics;
- increases in the scope of eligibility for customers to purchase IBTROZI at the discounted government price or to obtain government-mandated rebates on purchases of IBTROZI;
- changes in our cost of sales;
- the timing, cost and level of investment in our sales and marketing efforts to support IBTROZI sales;
- the timing and level of royalty payments under the RIF Agreement and Loan Agreement with Sagard;
- the scope, rate of progress, results and costs of drug discovery, preclinical development, laboratory testing and clinical trials for our product candidates;
- the number and development requirements of product candidates that we may pursue, and other indications for our current product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- the scope and costs of manufacturing development and commercial manufacturing activities;
- the cost associated with commercializing any approved product candidates;
- the cost and timing of developing our ability to establish sales and marketing capabilities, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining, enforcing and protecting our intellectual property rights, defending intellectual property-related claims and obtaining licenses to third-party intellectual property;
- our ability to establish and maintain collaborations on favorable terms, if at all; and
- the extent to which we acquire or in-license other product candidates and technologies and associated intellectual property, and payments required under such acquisitions or in-licenses.

We will require additional revenues or capital to complete our planned clinical development programs for our clinical stage product candidates as well as our preclinical product candidates to obtain regulatory approval. Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future product candidates, if approved.

In addition, we cannot guarantee that future financing will be available on a timely basis, 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 our issuance of additional securities, whether equity or debt, or the market perception that such issuances are likely to occur, could cause the market price of our Common Stock to decline. If we are unable to obtain funding on a timely basis on acceptable terms, we may be required to delay, reduce or terminate one or more of our research and development programs or the commercialization of IBTROZI or any of our other product candidates if approved. This could harm our business and could potentially cause us to cease operations.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, 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 when needed, we may be required to delay, reduce or terminate our product development or future commercialization efforts or grant rights to third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our earnings. Any new taxes could adversely affect our business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us, which could require us to pay additional taxes on a prospective or retroactive basis, as well as penalties, interest and other costs, including compliance costs. Legislation referred to as the OBBBA enacted in 2025, the Inflation Reduction Act enacted in 2022, the Coronavirus Aid, Relief, and Economic Security Act enacted in 2020, and the Tax Cuts and Jobs Act enacted in 2017 (the "Tax Act") made many significant changes to the U.S. tax laws. For example, for tax years beginning after December 31, 2024, the OBBBA restores the tax deductibility of domestic research and development expenses in the year incurred, which expenses had been required under the Tax Act to be capitalized and subsequently amortized over five years. The OBBBA did not change the tax treatment of expenses incurred in research and development activities conducted outside the United States, which expenses continue to be required to be capitalized and amortized over 15 years. We are evaluating the potential impacts this and other changes under the OBBBA may have on our business. Future guidance from the Internal Revenue Service and other tax authorities with respect to any such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation or sunset in future years. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

In addition, our tax obligations (including the cost of compliance) and effective tax rate could increase, including as a result of the base erosion and profit shifting ("BEPS") project that is being led by the Organization for Economic Co-operation and Development ("OECD"), and other initiatives led by the OECD. For example, the OECD is leading work on proposals, commonly referred to as "BEPS 2.0", which have made (and are expected to continue to make) important changes to the international tax system. These proposals include, among other measures, the imposition of a minimum effective corporate tax rate on certain multinational enterprises (referred to as "Pillar Two"). A number of countries have enacted, or are in the process of enacting, core elements of the Pillar Two rules (with further provisions expected to be enacted in the future). The OECD has issued (and is expected to continue to issue further) administrative guidance providing transition and safe harbor rules in relation to the implementation of the Pillar Two proposal. For example, on January 5, 2026, the OECD published details of a proposed "side-by-side" arrangement providing for, among other things, additional safe harbors for multinational groups headquartered in certain qualifying jurisdictions, which includes the U.S. Based on our current understanding of the minimum revenue thresholds, we currently expect to be outside the scope of the Pillar Two proposals but could fall within their scope in the future. We are monitoring developments (including considering our eligibility to qualify for the relevant safe harbor rules under the proposed "side-by-side" arrangement) and evaluating the potential impacts these new rules may have on our business.

Our ability to use our net operating loss carryforwards and certain other tax attributes to offset taxable income or taxes may be limited.

As of December 31, 2025, we had federal and state net operating loss ("NOL") carryforwards of $330.6 million and $440.5 million, respectively. U.S., federal NOLs incurred in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but such federal NOL carryforwards are permitted to be used in any taxable year to offset only up to 80% of taxable income in such year.

Separately, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, (the "Internal Revenue Code"), and corresponding provisions of state law, if a corporation undergoes an "ownership change," which generally is defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income or taxes may be limited. The completion of the 2021 merger of Nuvation Bio Inc. and Panacea Acquisition Corp., together with private placements and other transactions that have occurred since our inception, may have triggered such an ownership change pursuant to Section 382. We have not completed a Section 382 analysis, and therefore, there can be no assurances that our NOL carryforwards are not already limited. We also may experience ownership changes as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset U.S. federal taxable income may be subject to limitations, which potentially could result in increased future tax liability to us. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, this could harm our future operating results by effectively increasing our future tax obligations. In addition, due to changes in laws and regulations, including changes proposed or implemented by the current or a future U.S. presidential administration, such as alternative minimum taxes, or other unforeseen reasons, our existing net operating losses could become unavailable to reduce future income tax liabilities. Further, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California imposed limits on the usability of California state net operating losses to offset taxable income in tax years beginning after 2023 and before 2027.

Risks Related to our Indebtedness

Our level of indebtedness and debt service obligations could adversely affect our financial condition and may make it more difficult for us to fund our operations.

On March 3, 2025, we announced the closing of a non-dilutive financing of up to $250.0 million from entities affiliated with Sagard Healthcare Partners (collectively, "Sagard"). The financing is comprised of a $150.0 million (the "Investment Amount") synthetic royalty financing under the RIF Agreement and a $100.0 million senior secured term loan under the Loan Agreement. The Investment Amount and the first $50.0 million tranche of the term loan was funded on June 25, 2025, following FDA's approval of IBTROZI. The second $50.0 million tranche of the term loan will be available at our option until June 30, 2026, because we have achieved first U.S. commercial sale of IBTROZI.

Under the RIF Agreement, in exchange for the Investment Amount, we have agreed to make tiered royalty payments to Sagard on U.S. net sales of IBTROZI equal to 5.5% of annual U.S. net sales up to $600 million and 3.0% of annual U.S. net sales between $600 million and $1 billion. We will retain all annual U.S. net sales above $1 billion. Our obligation to make the royalty payments will cease upon the earliest occurrence of total royalty payments reaching 1.6 times of the Investment Amount by the calendar quarter ending on June 30, 2031, 1.75 times of the Investment Amount by the calendar quarter ending on June 30, 2034, or 2.0 times of the Investment Amount thereafter. To the extent we have not made royalty payments totaling at least 1.0 time of the Investment Amount by February 1, 2043, we will be required to make a true up payment in an amount equal to such shortfall (the "True Up Payment"). In addition, if certain events occur, including certain bankruptcy events, non-payment of Payments, a change of control, expiration or termination of certain intellectual property rights or marketing authorization, an out-license or sale of all of the rights in and to IBTROZI in the United States and (subject to applicable cure periods) non-compliance with the covenants in the RIF Agreement, we may be required to repurchase the synthetical royalty financing at a repurchase price ranging from 1.4 to 2.0 times of the Investment Amount, depending on the time of such event, less all royalty payments we made by then (the "Put/Call Payment").

Under the Loan Agreement, the term loan will bear interest at the secured overnight financing rate ("SOFR") plus a margin of 6.00%, subject to a 4.00% SOFR floor. There are no scheduled amortization payments associated with the term loan, with all outstanding principal due at maturity. If available, we must first satisfy ourselves that we will have access to future alternate sources of capital, such as from commercial revenues or the equity capital markets

or debt capital markets, in order to repay any additional principal borrowed, which we may be unable to do, in which case, our liquidity and ability to fund our operations may be substantially impaired.

All obligations under the Loan Agreement are secured by substantially all of our assets, including our intellectual property, and all obligations under the RIF Agreement are secured by accounts receivable arising from U.S. net sales of IBTROZI and intellectual property, product registrations and regulatory approvals related to commercialization and development of IBTROZI in the United States. Further, the terms of the Loan Agreement and the RIF Agreement place restrictions on our operating and financial flexibility, and limit or prohibit our ability to dispose of certain assets and engage in other significant transactions. This indebtedness may create additional financing risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing the outstanding debt obligations at maturity. As we draw down any of the tranches under the Loan Agreement, our indebtedness will increase, which would further increase our risk of being unable to pay off or refinance our outstanding debt obligations at maturity.

Our indebtedness could also have important negative consequences, including:

- we will need to make tiered royalty payments under the RIF Agreement, and under certain circumstances, the True Up Payment or the Put/Call Payment, and to repay the Loan Agreement by making payments of interest and principal, all of which will reduce the amount of cash available to finance our operations, our research and development efforts and other general corporate activities;
- our failure to comply with the obligations of our affirmative and restrictive covenants in the Loan Agreement and the RIF Agreement could result in an event of default that, if not cured or waived, would permit Sagard to accelerate our obligation to repay this indebtedness, and Sagard could seek to enforce their security interest against certain of our assets that are collateral; and
- under the RIF Agreement, upon occurrence of certain events, we may be required to repurchase the synthetical royalty financing at a repurchase price ranging from 1.4 to 2.0 times of the Investment Amount, depending on the time of such event, less all royalty payments we made by then. In addition, we may borrow additional capital in the future to fund clinical development and our future growth, including pursuant to the Loan Agreement or potentially pursuant to new arrangements with different lenders. To the extent additional debt is added to our current debt levels, the risks described above could increase.

The terms of the Loan Agreement and the RIF Agreement place restrictions on our operating and financial flexibility.

The Loan Agreement and the RIF Agreement collectively impose operating and other restrictions on us. Such restrictions will affect, and in many respects limit or prohibit, our ability and the ability of our subsidiaries to, among other things:

- dispose of certain assets;
- engage in mergers, acquisitions or consolidations;
- incur additional indebtedness;
- create liens on assets;
- enter into certain licensing transactions;
- make certain payments;
- pay dividends and make contributions or repurchase our capital stock; and
- engage in certain transactions with affiliates.

We may not have cash available in an amount sufficient to enable us to make interest, principal or other payments on our indebtedness when due.

Our ability to make scheduled interest payments on or to refinance our indebtedness depends on our future performance and ability to raise additional sources of cash, which is subject to economic, financial, competitive and other factors beyond our control. If we are unable to generate sufficient cash to service our debt, we may be required

to adopt one or more alternatives, such as selling assets, restructuring our debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. If we desire to refinance our indebtedness, our ability to do so will depend on the state of the capital and lending markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Failure to satisfy our current and future debt obligations under the Loan Agreement, the RIF Agreement, or to comply with certain covenants in such agreements could result in an event of default, the occurrence and continuance of which provides Sagard with the right to demand immediate repayment of all outstanding obligations under such agreements (and in the case of certain insolvency, liquidation, bankruptcy or similar events, automatically requires immediate repayment of all outstanding obligations under such agreements), and to exercise remedies against us and the collateral securing such agreements. These events of default include, among other things:

- failure to make payments required by the agreements;
- insolvency, liquidation, bankruptcy or similar events;
- failure to observe covenants under the Loan Agreement, the RIF Agreement, and ancillary collateral documents, which failure, in certain limited cases, is not cured within applicable time periods;
- withdrawal of FDA's authorization of IBTROZI and certain other regulatory actions;
- the occurrence of a material adverse change;
- material misrepresentations;
- certain cross-default of third-party indebtedness or certain default or termination events of hedging assessments;
- certain money judgments being entered against us which are not timely paid, discharged or stayed; and
- our assets are attached or seized.

In the event of default, the lenders could accelerate all of the amounts due under the Loan Agreement or the RIF Agreement, as applicable. Sagard could also exercise its rights to take possession and dispose of certain of our assets that are collateral.

In addition, under the RIF Agreement, if certain events occur, including certain bankruptcy events, non-payment of Payments, a change of control, expiration or termination of certain intellectual property rights or marketing authorization, an out-license or sale of all of the rights in and to IBTROZI in the United States and (subject to applicable cure periods) non-compliance with the covenants in the RIF Agreement, we may be required to repurchase the synthetical royalty financing at a repurchase price ranging from 1.4 to 2.0 times of the Investment Amount, depending on the time of such event, less all royalty payments we made by then.

Under such circumstances, we may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time of such acceleration. In that case, we may be required to delay, limit, reduce or terminate our IBTROZI commercialization efforts, our research and development efforts, or grant to others rights to develop and market IBTROZI. Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events.

The RIF Agreement place certain restrictions on our operational flexibility

The RIF Agreement contains covenants that impose on us certain obligations with respect to commercial effort, reporting, indemnification and other matters and certain restrictions with respect to intellectual property transfers, licensing, acquisitions, divestitures, and other actions. The RIF Agreement also limits our ability to create or incur liens or dispose of certain assets related to taletrectinib. If we want to early terminate the RIF Agreement, we will need to pay Sagard an amount ranging from 1.4 to 2.0 times of the Investment Amount (depending on the timing of the early termination and less all royalty payments we made by then), thereby limiting our ability to eliminate future applicability of the covenants contained in the RIF Agreement. Compliance with these covenants may limit our flexibility in operating our business and our ability to take actions that might otherwise be advantageous to us and our stockholders.

Risks Related to the Development of our Product Candidates

If we do not obtain regulatory approval for and successfully commercialize additional product candidates or we experience significant delays in doing so, we may incur significant losses.

Our business currently depends heavily on the successful development, regulatory approval and, if approved, commercialization of one or more of our current or future product candidates, such as safusidenib. We cannot be certain that any of these or any other product candidates will receive regulatory approval or will be successfully commercialized even if we receive regulatory approval. The research, testing, manufacturing, safety, efficacy, labeling, approval, sale, marketing and distribution of product candidates is, and will remain, subject to comprehensive regulation by the FDA and similar foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through preclinical studies and clinical trials that the product candidate is safe and effective for use in each target indication. The FDA and similar foreign regulatory authorities may not agree that the clinical data demonstrates safety and efficacy of our product candidates.

Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our preclinical studies or clinical trials. For example, based on clinical experience since February 2022, we have discontinued or deprioritized three clinical-stage programs. Failure to obtain regulatory approval for our product candidates will prevent us from commercializing and marketing our product candidates. The success of our product candidates will depend on several additional factors, including:

- successful completion of preclinical studies;
- successful initiation of clinical trials;
- successful patient enrollment in, and completion, of clinical trials that demonstrate their safety and efficacy;
- receiving marketing approvals from applicable regulatory authorities;
- obtaining, maintaining, protecting and enforcing patent, trade secret and other intellectual property rights and regulatory exclusivity for our product candidates;
- completing any post-marketing studies required by applicable regulatory authorities;
- making and maintaining arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates;
- establishing sales, marketing and distribution capabilities and successfully launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- the prevalence and severity of adverse events experienced with our product candidates;
- acceptance of our product candidates by patients, the medical community and third-party payors;
- maintaining a continued acceptable safety profile of the products following approval;
- obtaining and maintaining healthcare coverage and adequate reimbursement for our product candidates;
- competing effectively with other cancer therapies, including with respect to the sales and marketing of our product candidates, if approved; and
- obtaining licenses to any third-party intellectual property we deem necessary or desirable.

Many of these factors are beyond our control, including the time needed to adequately complete preclinical studies, clinical testing and the regulatory submission process, our ability to obtain and protect intellectual property rights and changes in the competitive landscape. It is possible that none of our current or future product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully complete clinical trials, obtain regulatory approval or, if approved, commercialize our product candidates, which would materially harm our business, financial condition, results of operations and prospects.

In addition, the clinical trial requirements of the FDA, the European Union, competent authorities of EU Member States, the MHRA, the NMPA and other comparable regulatory authorities and the criteria regulators may

use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates can be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates.

We are currently conducting, and may in the future conduct, clinical trials for current or future product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such clinical trials.

We are currently conducting clinical trials outside the United States, including in China, and we expect to continue to conduct clinical trials internationally in the future. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials 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 U.S. population and U.S. healthcare system practices and (ii) the clinical trials were performed by clinical investigators of recognized competence and pursuant to GCP; 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 inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCPs and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements for clinical data gathered outside of their respective jurisdictions. In addition, such foreign clinical trials are subject to the applicable local laws of the foreign jurisdictions where the clinical trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from clinical trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional clinical trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop being delayed or not receiving approval for commercialization in the applicable jurisdiction.

Our approach to the discovery and development of product candidates based on our DDC platform is unproven, and we do not know whether we will be able to develop any products of commercial value, or if competing technological approaches will limit the commercial value of our product candidates or render our platform obsolete.

The success of our business depends in part upon our ability to identify, develop and commercialize products based on our proprietary DDC platform, which leverages a novel and unproven therapeutic approach within the drug-conjugate class of anti-cancer therapies. We have not yet demonstrated safety or efficacy for any DDC product candidate. Our research methodology and novel approach to oncology using our DDC platform may be unsuccessful in identifying additional product candidates, and any product candidates based on our technology may be shown to have harmful side effects or may have other characteristics that may necessitate additional clinical testing, or make the product candidates unmarketable or unlikely to receive marketing approval. In addition, adverse developments with respect to one of our DDC platform-based programs may have a significant adverse impact on the actual or perceived likelihood of success and value of similar programs. For example, in November 2025, we announced the discontinuation of development of NUV-1511, our first DDC clinical product candidate, due to inconsistent efficacy.

In addition, the biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies. Our future success will depend in part on our ability to maintain a competitive position with our DDC platform. If we fail to stay at the forefront of technological change in utilizing our DDC platform to create and develop product candidates, we may be unable to compete effectively. Our competitors may render our DDC platform obsolete, or limit the commercial value of our product candidates, by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our drug discovery process that we believe we derive from our research approach and proprietary technologies. By contrast, adverse developments with respect to other companies that attempt to use a similar approach to our approach may adversely impact the actual or perceived value of our DDC platform and potential of our DDC platform-based product candidates. If any of these

events occur, we may be forced to abandon our development efforts for a program or programs, which would harm our business.

Our DDC platform-based product candidates are based on a novel technology, which makes it difficult to predict the time and cost of product candidate development.

We have concentrated our product research and development efforts on our novel DDC platform, and our future success depends in part on the successful development of product candidates arising from our DDC platform. There can be no assurance that any development problems we may experience in the future related to our DDC platform will not cause significant delays or unanticipated costs, or that such development problems can be efficiently solved. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all.

We may in the future develop product candidates in combination with other therapies and that may expose us to additional risks.

We may develop future product candidates for use in combination with one or more currently approved cancer 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 be subject to the risks that the FDA or similar foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate 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 may also evaluate our product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or similar foreign regulatory authorities. We will not be able to market and sell our product candidates we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval.

If the FDA or similar foreign regulatory authorities do not approve or revoke the approval of these other drugs, or if safety, efficacy, manufacturing or supply issues arise with the drugs we choose to evaluate in combination with our product candidates, we may be unable to obtain approval of or market our product candidates.

Clinical trials are very expensive, time-consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials.

The risk of failure for our product candidates is high. It is impossible to predict when or if any of our product candidates will prove safe or effective in humans or will receive regulatory approval. To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans for use in each target indication. Preclinical investigation and clinical testing is expensive and can take many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the preclinical investigation or clinical trial process. For example, in August 2022, we announced the discontinuation of development of our former lead program, NUV-422, following the emergence of a safety signal, uveitis, which is a form of inflammation of the eye.

In addition, the results of preclinical studies and earlier clinical trials may not be predictive of the results of later-stage preclinical studies or clinical trials. The results generated to date in preclinical studies for our product candidates do not ensure that later preclinical studies or clinical trials will demonstrate similar results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and earlier stage clinical trials. In later-stage clinical trials, we will likely be subject to more rigorous statistical analyses than in completed earlier stage clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in later-stage clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. 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 studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other clinical trial protocols, and the rate of dropout among clinical trial participants. If we fail to produce positive results in our planned preclinical studies or clinical trials of any of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be materially and adversely affected.

Interim, "topline," and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial.

We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

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

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

We may encounter substantial delays in our preclinical studies or clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate for its intended indications. Preclinical studies and clinical trials are expensive, time-consuming and uncertain as to outcome. We cannot guarantee that any preclinical studies or clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more preclinical studies or clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of preclinical or clinical development include:

- delays in conducting experiments or preclinical studies or unsatisfactory results from such experiments or studies;
- delays in reaching a consensus with regulatory authorities on trial design, dose optimization or dose selection;
- delays in reaching agreement or failing to agree on acceptable terms with prospective CROs and clinical trial sites;

- delays in opening sites and recruiting suitable patients to participate in our clinical trials;
- delays in enrollment due to travel or quarantine policies, or other factors, related to health epidemics, other pandemics or other events outside our control;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event, concerns with a class of product candidates or after an inspection of our clinical trial operations or trial sites;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

For instance, health epidemics and the measures taken in response by the governmental authorities could disrupt the supply chain and the manufacture or shipment of drug substances and finished drug products for our product candidates for use in our research and clinical trials, delay, limit or prevent our employees and CROs from continuing research and development activities, impede the ability of patients to enroll or continue in clinical trials, or impede testing, monitoring, data collection and analysis or other related activities, any of which could delay our clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations.

Any inability to timely and successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to achieve regulatory and commercialization milestones. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional testing to bridge our modified product candidate to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates, if approved, or allow our competitors to bring comparable drugs to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects.

Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our product candidates, we may:

- be delayed or unsuccessful in obtaining marketing approval;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, vary or suspend, their approval of the drug or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy, or REMS, or comparable foreign restrictions;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

Our drug development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all.

Further, we, the FDA or comparable foreign regulatory authorities, an Institutional Review Board, or an Ethics Committee may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with applicable regulatory requirements, including the FDA's current GCP and foreign equivalents, regulators find that we are exposing participants to unacceptable health risks or if the FDA or comparable

foreign regulatory authorities find deficiencies in our Investigational New Drugs, clinical trial applications or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be negatively impacted, and our ability to generate revenues from our product candidates may be delayed or eliminated entirely.

If we encounter continued or new difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We have experienced and may in the future experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including challenges resulting from health epidemics, labor shortages, and global supply chain interruptions. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size and health of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial site. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies rather than enroll patients in any future clinical trial.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our current or planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

If we or third parties are unable to successfully develop companion diagnostics for taletrectinib, safusidenib, or any of our other product candidates that are targeted therapies, or if we experience significant delays in doing so, we may not achieve marketing approval or realize the full commercial potential of such product candidates.

A key part of our development strategy for taletrectinib, safusidenib, and any of our other product candidates that are targeted therapies, is to identify subsets of patients with specific types of tumors that express specific genetic markers. Identification of these patients may require the development and use of companion diagnostics. The FDA generally will require either approval or clearance of the diagnostic at the same time the FDA approves the therapeutic product, or as a post-marketing commitment at the time of the therapeutic product's approval. For example, IBTROZI's approval in the U.S. is subject to a post-marketing commitment to develop a companion diagnostic. We do not have experience or capabilities in developing or commercializing diagnostics and plan to rely in large part on third parties to perform these functions. A companion diagnostic for ROS-1 positive NSCLC will require the conduct of a clinical bridging study with high sample ascertainment, as the TRUST-I and TRUST-II trials were conducted using multiple investigational devices.

In the EEA, companion diagnostics are regulated as IVDs and are governed by the IVDR. IVDs, including companion diagnostics, must conform with the GSPRs of the IVDR as a prerequisite to be able to affix the CE mark to devices, without which they cannot be marketed or sold in the EEA. To demonstrate compliance with the GSPR laid down in Annex I to the IVDR, and obtain the right to affix the CE mark, companion diagnostics must undergo a conformity assessment by a Notified Body. Depending on the relevant conformity assessment procedure, the Notified Body audits and examines the technical documentation and the quality system for the manufacture, design and final inspection of the medical devices. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the GSPRs. In addition, before issuing the CE Certificate of Conformity, the Notified Body will be required to seek a scientific opinion from the EMA or the national competent authority of the relevant EU Member State, as applicable, on the suitability of the companion diagnostic for use in relation to the medicinal product concerned. The CE Certificate of Conformity and the related conformity assessment process entitle the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and may require separate regulatory approval or certification prior to commercialization of the associated product candidate. If we or third parties are unable to successfully develop companion diagnostics for our product candidates, or experience delays in doing so:

- the development of these product candidates may be delayed because it may be difficult to identify patients for enrollment in our clinical trials in a timely manner;
- these product candidates may not receive marketing approval if their safe and effective use depends on a companion diagnostic; and
- we may not realize the full commercial potential of these product candidates that receive marketing approval if, among other reasons, we are unable to appropriately identify patients or types of tumors with the specific genetic alterations targeted by these product candidates.

Even if our product candidates and any associated companion diagnostics are approved or certified for marketing, the need for companion diagnostics may slow or limit adoption of our product candidates. Although we believe genetic testing is becoming more prevalent in the diagnosis and treatment of cancer, our product candidates may be perceived negatively compared to alternative treatments that do not require the use of companion diagnostics, due to either the additional cost of the companion diagnostic or the need to complete additional procedures to identify genetic markers prior to administering our product candidates.

If any of these events were to occur, our business and growth prospects would be harmed, possibly materially.

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

Because we have limited financial and managerial resources, we focus on research programs that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications, even those that we have begun investigating and that may have shown promise, that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial therapies or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

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 drug products is highly competitive. 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, specialty pharmaceutical and

biotechnology companies among others. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop therapies for the treatment of cancer. There are other companies working to develop therapies for the treatment of cancer including divisions of large pharmaceutical and biotechnology companies of various sizes. 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. 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.

We are developing our initial product candidates for the treatment of cancer. There are already a variety of available drug therapies marketed for cancer and some of the currently approved drug therapies are branded and subject to patent protection, and others are available on a generic basis. Many of these approved drugs are well established therapies and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic products. This may make it difficult for us to achieve our business strategy of replacing existing therapies with our product candidates.

Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop. In addition, most of these companies have substantially greater sales, marketing and other experience and reserves than we do. Competition may further increase as a result of advances in the commercial applicability of technologies for drug discovery and development and greater availability of capital for investment in cancer therapies.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving FDA approval for or commercializing drugs before we do, which would have an adverse impact on our business and results of operations.

The availability of our competitors' products could limit the demand and the price we are able to charge for any product candidate we commercialize, if any. The inability to compete with existing or subsequently introduced drugs would harm our business, financial condition, results of operations and prospects.

We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. The current and future use of product candidates by us in clinical trials, and the sale of IBTROZI and any other approved products in the future, may expose us to liability claims. These claims might be made by patients who use the product, healthcare providers, pharmaceutical companies or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend or settle, and could compromise the market acceptance of our product candidates or any prospects for commercialization of IBTROZI or our product candidates, if approved. For more information regarding the risks associated with intellectual property-related litigation, see "Risk Factors—Risks Related to Our Intellectual Property."

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen or rare side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates.

Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. As the expense of insurance coverage is increasing, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities

or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Even if we receive Fast Track designation or granting of other FDA expedited programs, or other comparable foreign expedited programs, for any of our product candidates, there is no guarantee that such product candidates will experience a faster regulatory review or obtain regulatory approval.

If a product is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product 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 receive Fast Track designation for any of our product candidates, we may not experience a faster development process, review or approval compared to conventional FDA approval timelines, and the FDA may still decline to approve such product candidates. The FDA may rescind the Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program or for any other reason. Similarly, the FDA's other expedited drug development programs (e.g., Breakthrough Therapy, Accelerated Approval, Priority Review) do not guarantee a product candidate's faster regulatory review or regulatory approval. The EMA has a similar program called PRIME.

Even if we receive Orphan Drug designation for any of our product candidates, we may be unable to maintain the benefits associated with such designation, including the potential for market exclusivity.

Regulatory authorities in some jurisdictions, including the United States and the EU, may designate drugs for relatively small patient populations as Orphan Drugs. Under the 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 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, Orphan Drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax credits for certain clinical trial costs and user-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 from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. The applicable period is seven years in the United States.

In the European Union, the European Commission grants orphan designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an orphan designation application. Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000 provides that a medicinal product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that: (1) the product is intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions; (2) either (a) such conditions affect not more than 5 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 developing the medicinal product; and (3) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the EU, or even if such method exists, the product will be of significant benefit to those affected by that condition. Orphan medicinal product designation entitles an applicant to incentives such as fee reductions or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. The period of market exclusivity is ten years during which the EMA cannot accept another marketing authorization application or accept an application to extend for a similar product and the European Commission cannot grant a marketing authorization for the same indication for a period of ten years. The period of market exclusivity may be extended by two years for orphan medicinal products that have also complied with an agreed Pediatric Investigation Plan. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product designation, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, a marketing authorization may be granted to a similar medicinal product with the same orphan indication during the 10 year period if: (i) if the applicant consents to a second original orphan medicinal product application, (ii) if the manufacturer of

the original orphan medicinal product is unable to supply sufficient quantities; or (iii) if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product.

Even if we receive Orphan Drug designation for any of our product candidates, there is no guarantee that we will obtain approval or Orphan Drug exclusivity for such product candidates. Even if we obtain Orphan Drug exclusivity for any of our product candidates, that exclusivity may not effectively protect the product candidates from competition because different therapies can be approved for the same condition and the same therapy could be approved for different conditions. Even after an Orphan Drug is approved, the FDA can subsequently approve the same drug for the same condition 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. Moreover, Orphan Drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Similarly, in the EU a marketing authorization may be granted to a similar medicinal product with the same orphan indication during the 10 year period if: (i) if the applicant consents to a second original orphan medicinal product application, (ii) if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. 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.

Risks Related to Our Dependence on Third Parties

We rely on third parties to perform the chemistry work associated with our drug discovery and preclinical activities and to conduct our preclinical studies and future clinical trials, and our business could be substantially harmed if these third parties cease performing services or perform in an unsatisfactory manner.

We do not have any laboratory facilities and have relied on CROs to perform most of the medicinal chemistry work associated with our drug discovery activities.

We also do not currently have the ability to independently conduct preclinical studies or clinical trials without outside assistance. We have relied on CROs to conduct all of our preclinical studies to date and intends to conduct our future clinical trials by leveraging expertise and assistance from CROs as appropriate. We plan to rely upon medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct or assist us in conducting GCP-compliant clinical trials on our product candidates properly and on time, and may not currently have all of the necessary contractual relationships in place to do so. Once we have established contractual relationships with such third-party CROs, we will have only limited control over their actual performance of these activities.

We and our CROs and other vendors are required to comply with cGMP, GCP, and good laboratory practice ("GLP"), which are regulations and guidelines enforced by the FDA, the competent authorities of EU Member States and any comparable foreign regulatory authorities for all of our product candidates in preclinical and clinical development. Regulatory authorities enforce these regulations through periodic inspections of trial sponsors, principal investigators, clinical trial sites and other contractors. Although we will rely on CROs to conduct any current or planned GLP-compliant preclinical studies and GCP-compliant clinical trials and has limited influence over their actual performance, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with our investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities. If we or any of our CROs or vendors fail to comply with applicable regulations, the data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA, the EMA and the European Commission, MHRA, NMPA or any other comparable foreign regulatory authority may require us to perform additional preclinical studies and clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that all of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced under cGMP requirements. We, our contract manufacturers, any future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA, the competent authorities of EU Member States, the MHRA, the NMPA or other comparable foreign regulatory authorities, to monitor and ensure compliance with cGMP. Despite our efforts to audit and verify regulatory compliance, one or more of our third-party manufacturing vendors may be found on regulatory inspection by the FDA, the competent authorities of EU Member States, the MHRA, the NMPA or other comparable foreign regulatory

authorities to be noncompliant with cGMP regulations. This may result in shutdown of the third-party vendor or invalidation of drug product lots or processes. In some cases, a product recall may be warranted or required, which would materially affect our ability to supply and market our drug products. Our failure to comply with these requirements may require us to repeat clinical trials, which would delay the regulatory approval process.

While we or our CROs have or will have agreements governing their activities, we will not be able to control whether or not they devote sufficient time and resources to our future chemistry work and preclinical and clinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other chemistry or drug discovery or development activities. We face the risk of potential unauthorized disclosure, infringement, misappropriation or other violation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors, and other third parties, to access and exploit our proprietary technology. CROs also may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property-related proceedings that could jeopardize or invalidate our proprietary information and intellectual property. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reason, our clinical trials or other drug discovery or development activities may be extended, delayed or terminated, the clinical data generated in our clinical trials may be deemed unreliable, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If our relationships with our CROs were to terminate, we might not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus, and could delay the discovery, development and commercialization of our product candidates. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can negatively impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a negative impact on our business and financial condition.

We do not have our own manufacturing capabilities and will rely on third parties to produce clinical and commercial supplies of taletrectinib, safusidenib, and our other current and future product candidates.

We have limited experience in drug formulation and manufacturing and do not own or operate, and we do not expect to own or operate, facilities for drug manufacturing, storage, distribution or testing. We obtain taletrectinib active pharmaceutical ingredients ("APIs") and drug product pursuant to long-term supply agreements. We currently rely upon a single source for taletrectinib API and are working to develop a second source. To date, we have obtained APIs and drug product for our investigational products mostly from single-source third-party CMOs. We are in the process of developing our supply chain for each of our investigational products and intend to put in place framework agreements under which CMOs will generally provide us with necessary quantities of API and drug product on a project-by-project basis based on our development needs. We seek to use a different CMO for each investigational product and will consider further diversification of drug product and supply organizations as circumstances warrant.

Third-party CMOs may be unable or unwilling to supply us with sufficient clinical and commercial grade quantities of our clinical materials due to production shortages or other supply interruptions resulting from health epidemics, because they are purchased by one of our competitors or another company that decides not to continue supplying us with these materials, or for other reasons. If one or more of these events occur and we are unable to timely establish an alternate supply from one or more third-party CMOs, we could experience delays in our development efforts as we locate and qualify new manufacturers. Under such circumstances, we may be required to receive drug substance for use on a purchase order basis, and as such, there can be no assurance that we actually receive sufficient quantities. See also the risk factor titled "—Our business, operations and clinical development plans and timelines and supply chain could be adversely affected by the effects of health epidemics, on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our CMOs, CROs, shippers and others."

Further, our reliance on third-party manufacturers exposes us to risks beyond our control, including the risk of:

- inability to meet our product specifications and quality requirements consistently;

- delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and quality issues, including related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for additional scale-up;
- failure of the manufacturer to comply with cGMP and similar foreign standards;
- inability to negotiate manufacturing agreements with third parties on commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on a limited number of sources, and in some cases, single sources for components, such that if we are unable to secure a sufficient supply of these drug components, we will be unable to manufacture and sell our product candidates in a timely fashion, in sufficient quantities or under acceptable terms;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or the issuance of a FDA Form 483 notice, warning letter, or cease and desist order;
- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our products under specified storage conditions and in a timely manner.

Some of these events could be the basis for FDA or comparable foreign regulatory authority action, including injunction, recall, seizure or total or partial suspension of production. In addition, our third-party manufacturers and suppliers are subject to FDA inspection and may be subject to inspections from comparable foreign regulatory authorities from time to time. Failure by our third-party manufacturers and suppliers to pass such inspections and otherwise satisfactorily complete the FDA approval regimen, or comparable foreign regulatory authorities' approval regimen, with respect to our product candidate may result in non-approval for our product candidates or regulatory actions such as the issuance of FDA Form 483 notices of observations, warning letters or injunctions or the loss of operating licenses. In addition, our third-party manufacturers and suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of waste products, and failure to comply with such laws and regulations could result in significant costs associated with civil or criminal fines and penalties for such third parties. Based on the severity of the regulatory action, our clinical or commercial supply of drug and packaging and other services could be interrupted or limited, which could harm our business.

In addition, our CMOs are or may be engaged with other companies to supply and manufacture materials or products for such companies, which also exposes our suppliers and manufacturers to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a contract supplier’s or manufacturer’s facility. If the FDA or a comparable foreign regulatory authority finds these facilities unsatisfactory in compliance with applicable regulations, does not approve these facilities for the supply or manufacture of our product candidates, or if it withdraws its approval in the future, we may need to find alternative supply or manufacturing facilities, which would negatively impact our ability to develop and obtain regulatory approval of our product candidates, or to market IBTROZI or our future approved products.

For later-stage clinical trials and commercialization, we will need to take steps to increase the scale of production of our product candidates, which may include transferring production to new third-party suppliers or manufacturers. In order to conduct larger or late-stage clinical trials for our product candidates and supply sufficient commercial quantities of the resulting drug product and our components, if that product candidate is approved for sale, our CMOs and suppliers will need to produce our product candidates in larger quantities, more cost effectively and, in certain cases, at higher yields than they currently achieve. These third-party contractors may not be able to successfully increase the manufacturing capacity for any such product candidates in a timely or cost-effective manner or at all. Significant scale up of manufacturing may require additional processes, technologies and validation studies, which are costly, may not be successful and which the FDA and comparable foreign regulatory authorities must review and

approve. In addition, quality issues may arise during those scale-up activities because of the inherent properties of a product candidate itself or of a product candidate in combination with other components added during the manufacturing and packaging process, or during shipping and storage of the APIs or the finished product. If our third-party CMOs are unable to successfully scale up the manufacture of any of our product candidates in sufficient quality and quantity and at commercially reasonable prices, and we are unable to find one or more replacement suppliers or manufacturers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality, and we are unable to successfully transfer the processes on a timely basis, the development of that product candidate and regulatory approval or commercial launch for any resulting products may be delayed, or there may be a shortage in supply, either of which could significantly harm our business, financial condition, results of operations and prospects.

Failure to maintain the License Agreement between Daiichi Sankyo Company, Limited and AnHeart Therapeutics Inc., dated December 7, 2018, as amended (the "Taletrectinib In-License Agreement") and the License Agreement between Daiichi Sankyo Company, Limited and AnHeart Therapeutics Inc., dated September 7, 2020 (the "Safusidenib In-License Agreement") could negatively impact our business.

Pursuant to the terms of the Taletrectinib In-License Agreement and the Safusidenib In-License Agreement, we received certain exclusive licenses to develop, manufacture and commercialize taletrectinib and safusidenib, respectively. Consequently, our ability to develop and commercialize taletrectinib and safusidenib depends on our ability to maintain these agreements with Daiichi Sankyo. We are subject to a number of other risks associated with our dependence on the Taletrectinib In-License Agreement and the Safusidenib In-License Agreement, including:

- Our obligations to make certain milestone and royalty payments;
- Our obligation to use commercially reasonable efforts to perform certain development and commercialization activities and to achieve certain milestones;
- Certain obligations not to develop or commercialize products that compete with taletrectinib or safusidenib; and
- Potential disputes between us and Daiichi Sankyo, including disagreements regarding the Taletrectinib In-License Agreement and the Safusidenib In-License Agreement.

If either the Taletrectinib In-License Agreement or the Safusidenib In-License Agreement is terminated early, we may be unable to pursue continued development, manufacture and commercialization of taletrectinib or safusidenib.

If we are not able to establish and maintain collaborations, we may have to alter some of our future development and commercialization plans.

Our product development programs and the commercialization of our product candidates will require substantial additional capital to fund expenses. The commercial rights to taletrectinib have been out-licensed in China, Japan, Europe and other territories, and we may enter into other collaboration agreements with pharmaceutical and biotechnology companies for the future development and potential commercialization of our product candidates. We will likely have limited control over the amount and timing of resources that our current and future collaborators dedicate to the development or commercialization of any product candidates we may seek to develop and commercialize with them. We cannot predict the success of any current or future collaboration that we may enter into.

We face significant competition in seeking appropriate collaborators, and a number of more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization experience and capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, European Commission, MHRA, NMPA or other similar foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, 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 collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. 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 collaborators.

We may not be able to negotiate collaboration agreements on a timely basis, on acceptable terms, or at all. Even if we are able to obtain a license to intellectual property of interest, we may not be able to secure exclusive rights, in which case others could use the same rights and compete with us. Our collaboration partners, if any, may not prioritize our product candidates or otherwise not effectively pursue the development of our product candidates which may delay, reduce or terminate the development of such product candidate, reduce or delay its development program or delay its potential commercialization. Further if we are unable to successfully obtain rights to required third-party intellectual property rights or maintain and protect the existing intellectual property rights we have, we may have to delay, reduce or terminate the development of our product candidates, 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. Doing so will likely harm our ability to execute our business plans. 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.

Risks Related to Regulatory Compliance

Health reform measures, including enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may charge for such product candidates.

The U.S. 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 product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "Affordable Care Act"), includes measures that have significantly changed the way healthcare is financed by both governmental and private insurers. There have been judicial, executive and congressional challenges and amendments to certain aspects of the Affordable Care Act . For example, on July 4, 2025, the One Big Beautiful Bill Act ("OBBBA"), was signed into law, which narrowed access to Affordable Care Act marketplace exchange enrollment and declined to extend the Affordable Care Act enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired Affordable Care Act subsidies. It is unclear how any such challenges and the healthcare reform measures of the second Trump administration will impact the Affordable Care Act and our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, on August 2, 2011, the Budget Control Act of 2011, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which began in 2013 and will remain in effect through 2032 unless additional congressional action is taken.

Recently, there has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. presidential executive orders, congressional inquiries and legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs.

We are unable to predict the future course of federal or state healthcare legislation in the U.S. directed at broadening the availability of healthcare and containing or lowering the cost of healthcare, particularly in light of the recent U.S. Presidential and Congressional elections. The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, the Centers for Medicare & Medicaid Services ("CMS") and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced the agreements with several pharmaceutical companies that require the drug manufacturer to offer, through a direct to consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions for example include (1) directing agencies to reduce workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (3) imposing tariffs of imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could, among others, impact the drug approval process and modify the Medicare Drug Price Negotiation Program, expand the orphan drug exclusion, and reduce Medicaid enrollment and funding. We expect additional health reform measures may be implemented in the future, particularly given the recent change in administration. These and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

The policies of the FDA and other regulatory authorities may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation (CTR), which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR introduces, among other changes, a centralized application system, coordinated review procedures, expanded reporting and increased transparency obligations. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our development plans.

Following a public consultation that began in 2022, the United Kingdom government has enacted new legislation to overhaul the clinical trials regulatory framework. In April 2025, the UK adopted an amendment to the Medicines for Human Use (Clinical Trials) Regulations 2004 intended to support a more streamlined and flexible regulation of clinical trials, remove unnecessary administrative burdens on trial sponsors, and protect the interests of trial participants. It also intends to bring the UK regulatory framework for clinical trials into closer alignment with the CTR. The amendment will become applicable on April 28, 2026 following a one-year transition period. While these changes introduce efficiencies and align with some principles of the EU's Clinical Trials Regulation (CTR), divergence between the United Kingdom and EU regulatory systems remains. Any significant divergence could affect the cost

and complexity of conducting clinical trials in the United Kingdom and may impact the acceptability of United Kingdom-based trial data for seeking marketing authorizations in the EU, and vice versa.

In addition, on December 11, 2025, the European Commission, the Parliament and the European Council reached a political agreement on a comprehensive overhaul of EU pharmaceutical legislation (the "Pharma Package"). The reform has been under negotiation since the European Commission submitted its proposal in April 2023. This package - comprised of a new directive and regulation to replace existing legislation – aims to modernize the EU framework. The political agreement is still subject to formal approval by the European Parliament and Council. If approved in the form proposed, the Pharma Package will, among other changes, reduce the baseline market protection period by one year, with limited opportunities for extensions, capped at a maximum of eleven years; reshape the incentives regime for orphan medicinal products, by introducing "breakthrough" orphan medicinal products – those addressing diseases with no available medicinal treatment – which will benefit from 11 years of market exclusivity; and expand the Bolar exemption to permit generic and biosimilar manufacturers to conduct preparatory activities for regulatory submissions, including pricing and reimbursement, and participate in procurement tenders while patent protection remains in force. A decrease in market exclusivity opportunities for our product candidates in the EU, combined with the expanded Bolar exemption, could open them to generic or biosimilar competition earlier than under the current regime, potentially impacting reimbursement status and the commercial prospects of our product candidates.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors and customers are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, health information privacy and security laws and other healthcare laws and regulations, including comparable foreign healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Our current and future operations are subject to various U.S. federal and state healthcare laws and regulations. Healthcare providers and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws may impact, among other things, our current business operations, including commercialization of IBTROZI, our clinical research activities, and proposed sales, marketing and education programs and constrain the business of financial arrangements and relationships with healthcare providers and other parties through which we may market, sell and distribute our products for which we obtain marketing approval. The laws that may affect our ability to operate include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal false claims, including the False Claims Act, which can be enforced through whistleblower actions, and Civil Monetary Penalties Laws, which, among other things, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, ("HIPAA"), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, ("HITECH"), and its implementing regulations, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by "covered entities", i.e. health plans, healthcare clearinghouses and certain healthcare providers, as well as their "business associates" and covered subcontractors that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;
- the U.S. Federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. federal legislation commonly referred to as Physician Payments Sunshine Act, enacted as part of the Affordable Care Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program to report annually to CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

In addition, some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance regulations promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and non-U.S. laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the delay, reduction, termination or restructuring of our operations. 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 to not be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded

healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business information, trade secrets, intellectual property, information we collect about trial participants in connection with clinical trials, and sensitive third-party information (collectively, sensitive data).

Our processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable protected health information. Numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services to the extent we become subject to these laws in the future. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, or CCPA, applies to personal data of California residents and requires businesses subject to the CCPA to provide specific disclosures in privacy notices and respond to requests of such individuals to exercise certain privacy rights. Similar laws are being considered in other states, as well as at the federal and local levels, and we expect more laws related to personal data to become effective in the future. These developments may further complicate compliance efforts and increase our legal risk and compliance costs.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the European Union's General Data Protection Regulation, or EU GDPR, the United Kingdom's GDPR, or UK GDPR, Australia's Privacy Act, and China's Personal Information Protection Law, or PIPL, impose strict requirements for processing personal data.

For example, under GDPR, companies may face private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests, temporary or definitive prohibitions on data processing and other corrective actions, or fines of up to the greater of 20 million Euros under the EU GDPR / 17.5 million pounds under the UK GDPR, or 4% of their worldwide annual 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 European Economic Area, or EEA, and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and

participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us 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 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. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the EU GDPR's cross-border data transfer limitations.

Additionally, the U.S. Department of Justice issued a rule entitled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restriction on certain data transactions involving countries of concern (e.g., China) and covered persons (i.e., individuals and who are designated as such by the U.S. Attorney General or considered "foreign persons" and are majority owned by, organized under the laws of, a primary resident in, or a contractor of, a covered person or country of concern, as applicable) that may impact certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to transfer data in connection with certain transactions or agreements.

We also publish privacy policies, marketing materials, and other statements, regarding data privacy and security. If these policies, materials, or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Obligations related to data privacy and security (and individuals' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties with whom we work (such as contract research organizations and clinical trial sites) may fail (or be perceived to have failed) to comply with such obligations, which could negatively impact our business operations. If we or the third parties with whom we work fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans or restrictions on processing personal data (including clinical trial data); orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process sensitive data or to operate in certain jurisdictions; limited ability to develop or

commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Risks Related to Our Intellectual Property

If we are unable to obtain, maintain, protect and enforce sufficient patent and other intellectual property rights for our product candidates and technology, or if the scope of patent and other intellectual property rights obtained is not sufficiently broad, we may not be able to compete effectively in our market.

Our success depends in significant part on our ability and the ability of any licensors and collaborators to obtain, maintain, protect and enforce patents and other intellectual property rights with respect to our product candidates and technology and to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others.

The patent prosecution process is uncertain, expensive and time-consuming. We and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our future licensors will fail to identify patentable aspects of our research and development output in time to obtain patent protection or fail to file patent applications covering inventions made in the course of development and commercialization activities before a competitor or another third party files a patent application covering, or publishes information disclosing, a same or similar, independently-developed invention. Such competitor's or other third party's patent application or published information may pose obstacles to or prohibit our ability to obtain patent protection or limit the scope of the patent protection we may obtain. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection in certain jurisdictions. In addition, publications of discoveries in the scientific literature often lag behind actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until approximately 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our future licensors were the first to conceive the inventions claimed in our owned or licensed patents or pending patent applications, or were the first to file for patent protection of such inventions.

The patent position of biotechnology and pharmaceutical companies generally is uncertain, involves complex legal and factual questions and is the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors' patent rights are uncertain. Our and our licensors' pending and future patent applications may not mature into patents or result in issued patents that protect our technology or product candidates, in whole or in part, or effectively exclude others from commercializing competitive technologies and product candidates. The patent examination process may require us or our licensors to narrow the scope of the claims of our pending and future patent applications, and therefore, even if such patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Our and our licensors' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover such technology. Any patents that we hold or in-license may be challenged or, circumvented by third parties or narrowed, invalidated or held unenforceable in litigation or post-grant proceedings. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

The patent protection we obtain for our product candidates and technology may be challenged or not sufficient to provide us with any competitive advantage.

Even if our owned or licensed patent applications issue as patents, the issuance of any such patents is not conclusive as to their inventorship, scope, validity or enforceability, and such patents may be challenged, invalidated, narrowed or held to be unenforceable, including in the courts or patent offices in the U.S. and abroad, or circumvented. We may be subject to a third-party preissuance submission of prior art to the USPTO, a federal court or equivalent foreign bodies, or become involved in opposition, derivation, revocation, re-examination, post-grant and inter partes

review or interference proceedings, or other similar proceedings, challenging our patent rights or the patent rights of others. An adverse determination as a result of any such submission, proceeding or litigation could reduce the scope of, invalidate, or render unenforceable, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we, or one of our licensors, may have to participate in interference or derivation proceedings declared by the USPTO to determine priority or ownership of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such proceedings and any other patent challenges may result in loss of patent rights, loss of exclusivity, loss of priority or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Moreover, there could be public announcements of the results of hearings, motions or other developments related to any of the foregoing proceedings. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our Common Stock to decline. Any of the foregoing could harm our business, financial condition, results of operations and prospects.

Moreover, some of our owned or in-licensed patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, who could market competing products and technology. In addition, we may need the cooperation of any such co-owners in order to enforce such patents against third parties, and such cooperation may not be provided to us.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to discover, develop and manufacture our product candidates, we must, at times, share certain of our trade secrets with them. We seek to protect our proprietary technology in part by entering into agreements containing confidentiality provisions, including if applicable, confidentiality agreements, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite these agreements with third parties, sharing trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could impair our competitive position and may harm our business.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets could impair our competitive position and have an adverse impact on our business.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful, and issued patents covering our technology and product candidates could be found invalid or unenforceable if challenged.

Competitors and other third parties may infringe, misappropriate or otherwise violate our issued patents or other intellectual property or the patents or other intellectual property of our licensors. In addition, our patents or the patents of our licensors may become involved in inventorship or priority disputes. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. To counter infringement or other unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or that our patents are invalid and/or unenforceable. In a patent infringement proceeding, a court may decide that a patent of ours is invalid and/or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using

the technology at issue on the grounds that our patents do not cover the technology. An adverse result in any litigation proceeding could put one or more of our owned or licensed patents at risk of being invalidated and/or held unenforceable, interpreted narrowly or interpreted in a manner that would not prevent competitors from entering the market. Further, we may find it impractical or undesirable to enforce our intellectual property against some third parties.

In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including, e.g., lack of novelty, obviousness, non-enablement or insufficient written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO or an equivalent foreign body, even outside the context of litigation. Potential proceedings include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our technology or any product candidates that we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on the applicable product candidates or technology covered by the patent rendered invalid and/or unenforceable. Such a loss of patent protection could materially harm our business, financial condition, results of operations and prospects.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the ownership or priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Such licenses may not be available on commercially reasonable terms, or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture and commercialization of one or more of the product candidates we may develop. In addition, if we or our licensors are unsuccessful in any inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights, such as exclusive ownership of, or the exclusive right to use, our owned or in-licensed patents. The loss of exclusivity or the narrowing of scope of our owned and/or licensed patents could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations or prospects. Even if we are successful in any of the foregoing disputes, it could result in substantial costs and be a distraction to management and other employees. 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 or proceeding.

Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, more likely to be able to sustain the costs of complex patent litigation or proceedings 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, misappropriating or otherwise violating our intellectual property. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims could result in substantial costs and diversion of management resources, which could harm our business. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs or in-license needed technology or other product candidates. There could also be public announcements of the results of the hearing, motions or other interim proceedings or developments. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our Common Stock to decline. Any of the foregoing events could harm our business, financial condition, results of operations and prospects.

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

Filing, prosecuting, maintaining, defending and enforcing patents and other intellectual property rights on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual

property rights in some countries outside the U.S. can be less extensive than those in the U.S. As such, we may choose not to seek to protect our intellectual property in certain jurisdictions, which could leave us without recourse to prevent competitive products from being manufactured or commercialized in such jurisdictions. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S.. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries or from selling or importing products made using our inventions in all jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection or other intellectual property rights to develop their own products and may export otherwise infringing, misappropriating or violating products to territories where we have patent or other intellectual property protection, but enforcement rights are not as strong as those in the U.S.. 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.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property rights, which could make it difficult for us to stop the infringement, misappropriation or other violation of our intellectual property rights generally. Proceedings to enforce our intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

Many countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license, which could adversely affect our business, financial condition, results of operations and prospects.

We may not identify relevant third-party patents or pending patent applications or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop and market our product candidates.

We are developing certain product candidates in highly competitive areas and cannot guarantee that any patent searches or analyses that we may conduct, including the identification of relevant patents or pending patent applications, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending patent application in the U.S. and abroad that is or may be relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the U.S. remain confidential until patents issue. Patent applications in the U.S. and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patents or pending patent applications covering our product candidates could have been or may be filed in the future by third parties without our knowledge. Additionally, patents and pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the manufacturing or use of our product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or pending patent application or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the U.S. or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents or pending patent applications may negatively impact our ability to develop and market our product candidates.

If we fail to identify or correctly interpret relevant patents or pending patent applications or if we are unable to obtain licenses to relevant patents or pending patent applications, we may be subject to infringement claims. We

cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, potentially including in the form of future royalties, which may be significant, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could adversely affect our business, financial condition, results of operations and prospects.

If we are unable to obtain licenses from third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, our business could be harmed.

It may be necessary for us to use the patented or other proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license or ownership from these third parties. The licensing or acquisition of third-party intellectual property rights is a competitive area, and more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources or greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. If we are unable to license or acquire such intellectual property or technology, or if we are forced to in-license such intellectual property or technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, or the cost of development, manufacture or commercialization may be materially increased, which could materially harm our business, and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

If we fail to comply with our obligations under any future license agreements, such counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or commercialize, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, or impede, delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements. If we were to lose our rights to licensed intellectual property, we may not be able to continue developing or commercializing our product candidates, if approved. If we breach any of the agreements under which we license the use, development and commercialization rights to our product candidates or technology from third parties or, in certain cases, we fail to meet certain development deadlines, we could lose license rights that are important to our business.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, and a given patent may be subject to other term adjustments, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive products, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, 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 Act of 1984, referred to as the Hatch-Waxman Amendments, and one or more of our foreign patents may be eligible for patent term extension under similar legislation, for example, in the European Union. In the U.S., the Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering

an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process provided other requirements are met. However, there are no assurances that the FDA, USPTO or any comparable foreign regulatory authority or national patent office will grant such extensions, in whole or in part and the length of any available extension may vary based on a number of factors. For example, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened, and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations and prospects could be adversely affected.

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

Obtaining and enforcing patents in the pharmaceutical industry is inherently uncertain, due in part to ongoing changes in the patent laws. Depending on decisions by Congress, the federal courts, and the USPTO and equivalent institutions in other jurisdictions, the laws and regulations governing patents, and interpretation thereof, could change in unpredictable ways that could weaken our and our licensors' or collaborators' ability to obtain new patents or to enforce existing or future patents. For example, in recent years the U.S. Supreme Court has ruled on several patent cases that have been interpreted to have either narrowed the scope of patent protection or weakened the rights of patent owners in certain situations. Therefore, there is increased uncertainty with regard to our and our licensors' or collaborators' ability to obtain patents in the future, as well as uncertainty with respect to the value of patents once obtained.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents. Assuming that other requirements for patentability are met, prior to March 16, 2013, in the U.S., the first to invent the claimed invention was entitled to the patent, while outside the U.S., the first to file a patent application was entitled to the patent. On March 16, 2013, under the Leahy-Smith America Invents Act enacted in September 2011 (the "Leahy-Smith Act"), the U.S. transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications are prosecuted and may also affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, particularly the first inventor-to-file provisions. Accordingly, it is not 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 increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents, all of which could harm our business, financial condition, results of operations and prospects.

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 if we fail to comply with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on any issued patents and certain pending patent applications are required to be paid to the USPTO or foreign patent agencies in several stages over the lifetime of a patent. In certain circumstances, we may rely on our licensors to pay these fees. The USPTO and various foreign patent agencies also require compliance with a number of procedural, documentary, fee

payment and other similar requirements during the patent application and prosecution process. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official communications within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in irrevocable abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we or our licensors or collaborators fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market with similar or identical products or technology, which would harm our business, financial condition, results of operations and prospects.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could negatively impact the success of our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, including re-examination, interference, post-grant review, inter partes review or derivation proceedings, or other similar proceedings, before the USPTO, a federal court or an equivalent foreign body. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. In the event that any of these patents were asserted against us, we believe that we would have defenses against any such action, including that such patents are invalid and/or unenforceable, that our product candidates do not infringe such patents, or that we would be able to replace such technology with alternative, non-infringing technology. However, if any such patents were to be asserted against us and our defenses to such assertion were unsuccessful and such alternative technology was not available or technologically or commercially practical, unless we obtain a license to such patents, we could be liable for damages, which could be significant and include treble damages and attorneys' fees if we are found to willfully infringe such patents, and we could be precluded from commercializing any product candidates that were ultimately held to infringe such patents. Any potential future legal proceedings relating to these patents could cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. If we are unsuccessful in our challenges to these patents and become subject to litigation or are unable to obtain a license on commercially reasonable terms with respect to these patents, it could harm our business, financial condition, results of operations and prospects.

Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that third-party patents asserted against us are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any product candidates we may develop and any other product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, and we are unsuccessful in demonstrating that such rights are invalid or unenforceable, we could be required to obtain a license from such a third party in order to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease commercializing the infringing technology or product candidates. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties and other fees, redesign our infringing drug or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Claims that we have misappropriated the confidential information or trade secrets of

third parties could have a similar negative impact on our business. Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

We may be subject to claims by third parties asserting that we or our employees have infringed upon, misappropriated or otherwise violated their intellectual property rights, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at other biotechnology or pharmaceutical companies. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of others, such as any such individual's former employer. Litigation may be necessary to defend against these claims.

In addition, we or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives, develops or reduces to practice intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in litigating such claims, litigation could result in substantial costs, delay development of our product candidates and be a distraction to management. Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

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

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our Common Stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development collaborations that would help us commercialize our product candidates, if approved. Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

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

We rely on trade secrets and agreements containing confidentiality obligations to protect our unpatented know-how, technology and other proprietary information and to maintain our competitive position. With respect to our research and development programs, we consider trade secrets and know-how to be one of our important sources of intellectual property, including our extensive knowledge of certain drug delivery techniques and drug conjugation. Trade secrets and know-how can be difficult to protect. We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may

breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U.S. are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

We may not be able to protect and enforce our trademarks and trade names, or build name recognition in our markets of interest thereby harming our competitive position.

We intend to rely on both registered and common law rights for our trademarks. We have applied to register certain of our trademarks with the USPTO and trademark authorities in certain other countries and may in the future seek to register additional trademarks in the U.S. or other countries. Our current and future trademark applications may not mature to registration in a timely fashion or at all, and our registered trademarks may not be maintained or enforced. In the U.S. and some foreign jurisdictions, our ability to obtain and maintain trademark registrations and acquire enforceable trademark rights depends on making use of our marks in commerce, meaning we must make a certain amount of progress, depending on the jurisdiction, in our clinical studies or in the commercialization of our products. If we fail to satisfy these requirements or any other requirements of applicable regulatory authorities, we may not have enforceable trademark rights or registrations in such jurisdictions.

In addition, the registered or unregistered trademarks or trade names that we own may be challenged, infringed, circumvented, declared generic, lapsed or determined to be infringing on or dilutive of other marks. We may be unable to develop any enforceable trademark rights in relevant countries, or to protect the rights that we do develop. We may be forced to stop using our trademarks or trade names, which we need for name recognition by potential partners and customers in our markets of interest, and spend time and money rebranding. In addition, third parties have filed, and may in the future file, for registration of trademarks similar or identical to our trademarks, thereby impeding our ability to build brand identity and possibly leading to market confusion. If they succeed in registering or developing common law rights in such trademarks, and if we are not successful in enforcing our rights, we may not be able to use these trademarks to develop brand recognition of our company, technologies, products or services. In addition, there could be potential trade name or trademark infringement litigation brought against us by owners of other trademarks that incorporate variations of our registered or unregistered trademarks or trade names.

During the trademark registration process, we may receive office actions from the USPTO or from comparable agencies in foreign jurisdictions refusing to register our trademarks. Although we would be given an opportunity to respond to those refusals, we may be unable to overcome them. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may in the future be filed against our trademark applications or registrations, and our trademark applications or registrations may not survive such proceedings. In addition, third parties may file first for our trademarks or similar variations thereof in certain countries. If they succeed in registering such trademarks, and if we are not successful in challenging such third-party rights, we may not be able to use these trademarks to market our products in those countries. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would. If we are unable to establish name recognition based on our trademarks and trade names, we may be unable to compete effectively, which could have an adverse effect on our business, financial condition, results of operations and prospects.

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 any product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we own or license now or in the future;

- we, or our current or future licensors, might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or license now or in the future;
- we, or our current or future licensors, 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 pending owned or licensed patent applications or those that we may own or license in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by other persons;
- our competitors might conduct research and development activities in the U.S. under FDA-related safe harbor patent infringement exemptions and/or 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 or pending patent applications of others may harm our business; and
- we may choose not to file for patent protection in order to maintain certain trade secrets or know-how, and a third party may subsequently file for and obtain a patent covering such intellectual property.

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

Risks Related to Our Business Operations, Employee Matters and Managing Growth

Disruptions at the FDA and other government agencies caused by layoffs, funding shortages or global health concerns could negatively impact our business.

The ability of the FDA to review proposed clinical trials or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, including executive and congressional priorities, the impacts of which are inherently fluid and unpredictable. Disruptions at the FDA and other agencies may slow the time necessary for new product candidates to be reviewed and/or approved, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. In addition, the current administration has implemented substantial reductions in force at various government agencies including the FDA, which could significantly reduce the FDA's capacity to perform its functions in a manner consistent with its past practices and could negatively impact our business.

Our business, operations and clinical development plans and timelines and supply chain could be adversely affected by the effects of health epidemics, on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our CMOs, CROs, shippers and others.

Our business could be adversely affected by health epidemics wherever we have clinical trial sites or other business operations. In addition, health epidemics could cause significant disruption in the operations of CMOs, CROs and other third parties upon whom we rely. For example, the COVID-19 pandemic presented a substantial public health and economic challenge around the world and affected employees, patients, communities and business operations, as well as the U.S. economy and financial markets. Geographic regions imposed "shelter-in-place" orders, quarantines or similar orders or restrictions to control the spread of epidemic disease. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

We are dependent on a worldwide supply chain for products to be used in our clinical trials and, if approved by the regulatory authorities, for commercialization. Quarantines, shelter-in-place and similar government orders, or the expectation that such orders, shutdowns or other restrictions could occur may impact personnel at third-party manufacturing facilities in the U.S. and other countries, or the availability or cost of materials or supplies, which could disrupt our supply chain or our ability to enroll patients in or perform testing for our clinical trials. In addition, closures of transportation carriers and modal hubs could materially impact our clinical development and any future commercialization timelines.

If our relationships with our suppliers or other vendors are terminated or scaled back as a result of health epidemics, we may not be able to enter into arrangements with alternative suppliers or vendors or do so on commercially reasonable terms or in a timely manner. Switching or adding additional suppliers or vendors involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new supplier or vendor commences work. As a result, delays generally occur, which could adversely impact our ability to meet our desired clinical development and any future commercialization timelines. Although we carefully manage our relationships with our suppliers and vendors, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects. See "Risk Factors—Risks Related to Our Dependence on Third Parties."

In addition, our clinical trials may be affected by health epidemics. In the future, clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward such health epidemics or concerns among patients about participating in clinical trials during a health epidemic and public health measures imposed by the respective national governments of countries in which the clinical sites are located. Some patients may have difficulty following certain aspects of clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our inability to successfully recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to epidemic disease or experience additional restrictions by their institutions, city or state governments could adversely impact our clinical trial operations.

Health epidemics may lead to disruption and volatility in the global capital markets, which increases the cost of, and adversely impacts access to, capital and increases economic uncertainty. Health epidemics may also result in volatile trading prices for the Common Stock of biopharmaceutical companies. To the extent health epidemics adversely affect our business, financial results and value of our Common Stock, it may also affect our ability to access capital, which could in the future negatively affect our liquidity.

Our future success depends on our ability to retain Dr. Hung and our other key employees, consultants and advisors and to attract, retain and motivate qualified personnel.

We are highly dependent on the management, research and development, clinical, financial and business development expertise of Dr. Hung and our executive officers, as well as the other members of our scientific, clinical and commercial teams. Although we have employment offer letters with each of 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 employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we are successful in obtaining marketing approval for our product candidates, commercial personnel, is critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

In particular, in light of Dr. Hung's central role in the discovery of all of our current product candidates, our ongoing discovery activities and development programs, the recruitment of our other executives and key employees and all other aspects of our strategy and operations, we believe our loss of Dr. Hung's services for any reason would severely impair our business and prospects. 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 for and commercialize our product candidates.

Competition to hire qualified personnel in our industry 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. Furthermore, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other

confidential information, or that their former employers own their research output. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited, and could harm our business, financial condition, results of operations and prospects.

We expect to expand our development, regulatory, 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 298 employees. As our preclinical and clinical development progresses, we expect to experience growth in the number of our employees and the scope of our operations, particularly in the areas of research, clinical operations, regulatory affairs, general and administrative, 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.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or unauthorized activities that violates (1) the laws, regulations and guidance of the FDA, the European Commission, the EMA, the MHRA, NMPA and other similar regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (2) manufacturing standards, (3) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the U.S. and abroad and (4) laws that require the true, complete and accurate reporting of financial information or data. 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. Misconduct by these parties could also involve the improper use of individually identifiable information, including information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product candidates, which could result in regulatory sanctions and serious harm to our reputation.

We have adopted a code of business conduct and ethics, 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 be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government 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 significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm and the delay, reduction, termination or restructuring of our operations.

If our information technology systems or those of third parties with whom we work, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

In the ordinary course of business, we and the third parties with whom we work, process sensitive data, and, as a result, we and the third parties with whom we work face a variety of evolving threats that could cause security incidents. Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties upon with whom we work. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties with whom we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services.

We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by artificial intelligence ("AI"), telecommunications failures, earthquakes, fires, floods, and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Remote work has increased risks to our information technology systems and data, as more of our personnel utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit or in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, our reliance on third parties could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on various third parties and technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, personnel email, and other functions. We also rely on third parties to provide other products, services, parts, or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties with whom we work experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if such third parties fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks

and systems. For example, threat actors may use an initial compromise of one part of our environment to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.

We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties upon which we rely). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties with whom we work. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our services.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.

Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, regulators, and investors, of security incidents, or to implement other requirements, such as providing credit monitoring. Such disclosures and compliance with such requirements are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may negatively impact our ability to grow and operate our 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 data privacy and security obligations. We cannot be sure that our insurance coverage, if any, will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive data about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive data of the Company could be leaked, disclosed, or revealed as a result of or in connection with our personnel's or vendors' use of generative AI technologies.

Risks Related to Doing Business in China and Our International Operations

International trade policies, including tariffs, sanctions and trade barriers, including changes in the political and economic policies and relations between the U.S. and China, have adversely impacted and may continue to adversely impact our business, financial condition, results of operations and prospects.

We operate in a global economy, and our business depends on a global supply chain for the development, manufacturing, and distribution of our pharmaceutical products, and for the advancement of our preclinical and clinical development programs. There is inherent risk based on the complex relationships among the U.S. and the countries in which we conduct our business, and due to our operations in China, such that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations.

We import taletrectinib, safusidenib and other materials that we source from China. Tariffs have been imposed on these materials, and additional tariff policies on pharmaceutical products could materially increase our costs and

reduce our profitability, including as a result of our inability to adjust pricing in formulary-based markets. Recent and potential future changes in international trade policies, particularly regarding U.S.-China trade relations and pharmaceutical-specific tariffs, present material risks to our operations and financial performance.

The current international trade and regulatory environment is subject to significant ongoing uncertainty. The ongoing trade tensions between the U.S. and other jurisdictions have resulted in multiple rounds of tariffs and anticipated tariffs affecting pharmaceuticals and pharmaceutical ingredients, including finished drug products, manufacturing equipment, and related supplies. The Bureau of Industry and Security, U.S. Department of Commerce, has initiated an investigation to determine whether pharmaceutical ingredients, including finished drug product, manufactured outside the United States pose a national security risk and should be subject to additional tariffs. Unlike consumer goods, pharmaceuticals face unique regulatory constraints that make rapid supply chain adjustments particularly difficult and costly. Should current tariffs hold or additional tariffs be imposed, our costs will rise significantly, and it would be difficult and costly to qualify alternative sources within other jurisdictions with lower tariff rates or within the United States, as developing and qualifying alternative sources typically requires up to two years, with substantial investment and regulatory approval requirements. Moreover, the dynamic and unpredictable tariff and trade landscape creates substantial uncertainty and significant planning challenges for our operations. Changes in tariff classifications, country-of-origin requirements, or customs procedures can occur with limited notice. This uncertainty complicates our long-term investment decisions regarding manufacturing facilities, supply chain optimization, and research and development locations.

We do not have our own manufacturing capabilities and rely, and will rely, on third parties, including Asymchem, Wuxi STA and Wuxi AppTec in China, to produce clinical or commercial supplies of taletrectinib, clinical supplies of safusidenib and potentially other future product candidates. In addition, we conduct research activities and have business operations both in the U.S. and China, and any unfavorable government policies on cross-border relations and/or international trade, including increased scrutiny on companies with certain operations based in China, capital controls or tariffs, may affect the competitive position of our products and product candidates, the hiring of scientists and other research and development personnel, the demand for our products and product candidates, our ability to raise capital, and our ability to sell IBTROZI or any of our product candidates that receives marketing approval in certain countries. Moreover, the dynamic and unpredictable tariff and trade landscape creates substantial uncertainty and significant planning challenges for our operations. Changes in tariff classifications, country-of-origin requirements, or customs procedures can occur with limited notice. This uncertainty complicates our long-term investment decisions regarding manufacturing facilities, supply chain optimization, and research and development locations.

Unlike many industries, our ability to pass increased costs to customers is limited by the structure of pharmaceutical pricing and reimbursement systems. Formularies that include IBTROZI have pricing established through annual or multi-year contracts with commercial, third-party payors and pharmacy benefit managers, and reimbursement methodologies established by government programs, such as Medicare. These arrangements typically include fixed pricing terms that were negotiated prior to the implementation of the recently announced tariffs. As a result, and depending on the timing and scope of the implementation of these tariffs, cost increases due to tariffs may be difficult or impossible to pass through to customers until the next negotiation cycle, which could be up to 36 months away.

Current or future tariffs will result in increased research and development expenses, including with respect to increased costs associated with APIs, raw materials, laboratory equipment and research materials and components. We cannot at this time predict the ultimate impact of tariffs and trade restrictions and anticipate that our cost of goods will be adversely affected to some degree, depending on the ultimate scope and duration of tariffs and trade restrictions imposed. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Given the nature of our product candidates, ongoing establishment of additional sources of manufacturing supply outside of China is a time-consuming process making it difficult for us to react quickly to a rapidly changing environment. If there are delays in qualifying new suppliers or facilities or a new supplier is unable to meet regulatory requirements for approval, and if it becomes necessary to source material from such new supplier, there could be a shortage of the affected products for the marketplace or for use in clinical studies, or both, which could negatively impact our anticipated revenues and could potentially cause us to breach contractual obligations with customers. Moreover, these tariffs could introduce significant transfer pricing challenges for us, including adapting our transfer pricing arrangements to account for increased costs associated with importing goods and implementing pricing changes in a manner that complies with applicable customs and transfer pricing rules, which we may be unable to do in a timely manner or at all, particularly given the current international trade and tariff fluidity, which could

result in the modification or elimination of the tax deductibility of various currently deductible payments and otherwise increase the tax burden of our operating or being a resident in a particular country. Increased costs and extended commercialization and development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence and negatively impact our business, results of operations, financial condition and growth prospects.

The complexity of announced or future tariffs may also increase the risk that we or our customers or suppliers may be subject to civil or criminal enforcement actions in the U.S. or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees, customers and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions, or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the U.S. and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs and complexity to our business. In particular, the Chinese government has implemented various measures to encourage economic development and guide the allocation of resources, which may benefit the overall Chinese economy but may have a negative effect on us. Due to our operations in China, any future Chinese, U.S. or other rules and regulations that place restrictions on capital raising or other activities by companies with operations in China could negatively affect our business and results of operations. If the business environment in China deteriorates from the perspective of domestic or international investment, or if relations between China and the U.S. or other governments deteriorate and geopolitical tensions between China and the U.S. increase, our business in China and the U.S. may be adversely impacted.

Further, the continued threats of new or increased tariffs, sanctions, trade restrictions and trade barriers as well as ongoing changes in U.S. and foreign government trade policies, including potential modifications to existing trade agreements, have had and may continue to have a generally disruptive impact on the global economy and, therefore, may negatively impact revenues. Given the volatility and uncertainty regarding the scope and duration of such tariffs and other aspects of U.S. and foreign government trade policies, the ultimate impact on our operations and financial results is uncertain and could be significant. In any event, further trade restrictions and export regulations, new or increased tariffs, new laws, regulations or executive orders, or further retaliatory measures, could increase our supply chain complexity and/or costs, decrease our margins, reduce the competitiveness of any of our product candidates, or restrict our ability to sell products or purchase necessary equipment and supplies. Any of these factors could have a material adverse effect on our business, financial condition, results of operations and prospects.

Trade disputes, tariffs, restrictions and other political tensions between the U.S. and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could have a material adverse effect on our business, financial condition, and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects. In addition, tariffs and other trade developments have heightened and may continue to heighten the risks related to the other risk factors described elsewhere in this Annual Report on Form 10-K.

Compliance with China's new Data Security Law, Cyber Security Law, Cybersecurity Review Measures, Personal Information Protection Law, regulations and guidelines relating to the multi-level protection scheme on cyber security and any other future laws and regulations may entail significant expenses and could affect our business.

China has implemented or will implement rules and is considering a number of additional proposals relating to data protection. China's new Data Security Law took effect in September 2021. The Data Security Law provides that the data processing activities must be conducted based on "data classification and hierarchical protection system" for the purpose of data protection and prohibits entities in China from transferring data stored in China to foreign law enforcement agencies or judicial authorities without prior approval by the Chinese government.

Additionally, China's Cyber Security Law, promulgated by the Standing Committee of the National People's Congress in 2016 and came into effect in 2017, and the Administrative Measures for the Hierarchical Protection of Information Security promulgated by the Ministry of Public Security, National Administration of State Secrets

Protection, State Cryptography Administration and other government authority in 2007, requires companies to take certain organizational, technical and administrative measures and other necessary measures to ensure the security of their networks and data stored on their networks. Specifically, the Cyber Security Law provides that China adopt a multi-level protection scheme ("MLPS"), under which network operators are required to perform obligations of security protection to ensure that the network is free from interference, disruption or unauthorized access, and prevent network data from being disclosed, stolen or tampered. Under the MLPS, entities operating information systems must have a thorough assessment of the risks and the conditions of their information and network systems to determine the level of the entity's information and network systems. These levels range from the lowest Level 1 to the highest Level 5 pursuant to a series of national standards on the grading and implementation of the classified protection of cyber security. The grading result will determine the set of security protection obligations that entities must comply with. Entities classified as Level 2 or above should report the grade to the relevant government authority for examination and approval.

In 2021, the Cyberspace Administration of China ("CAC") published a draft revision to the existing Cybersecurity Review Measures for public comment (the "Revised Draft CAC Measures"). In 2022, together with 12 other Chinese regulatory authorities, the CAC released the final version of the Revised Draft CAC Measures (the "Revised CAC Measures"), which came into effect in 2022. Pursuant to the Revised CAC Measures, critical information infrastructure operators procuring network products and services, and online platform operators (as opposed to "data processors" in the Revised Draft CAC Measures) carrying out data processing activities which affect or may affect national security, shall conduct a cybersecurity review pursuant to the provisions therein. In addition, online platform operators possessing personal information of more than one million users seeking to be listed on foreign stock markets must apply for a cybersecurity review. In 2024, the CAC further published the Regulations on Network Data Security Management (the "Network Data Management Regulations"), under which network data processors refer to individuals and organizations who determine the data processing activities in terms of the purpose and methods at their discretion. The Network Data Management Regulations specify that network data processors shall be subject to cybersecurity review if their data processing activities affect or may affect Chinese national security.

As of the date of this report, we have not received any notice from any Chinese regulatory authority identifying us as a "critical information infrastructure operator," "online platform operator" or "network data processor" that are subject to the cybersecurity review procedures pursuant to the Revised CAC Measures and the Network Data Management Regulations. Based on our understanding of the Revised CAC Measures, and the Network Data Management Regulations, we do not expect to become subject to cybersecurity review by the CAC for issuing securities to foreign investors because: (i) the clinical and preclinical data we handle in our business operations, either by its nature or in scale, do not normally trigger significant concerns over PRC national security; and (ii) we have not processed, and do not anticipate to process in the foreseeable future, personal information for more than one million users or persons. However, there remains uncertainty as to how the Revised CAC Measures, and the Network Data Management Regulations, will be interpreted or implemented; for example, neither the Revised CAC Measures nor the Network Data Management Regulations provides further clarification or interpretation on the criteria for determining those activities that "affect or may affect national security" and relevant Chinese regulatory authorities may interpret it broadly. Furthermore, there remains uncertainty as to whether the Chinese regulatory authorities may adopt new laws, regulations, rules, or detailed implementation and interpretation in relation, or in addition, to the Revised CAC Measures and the Network Data Management Regulations. While we intend to closely monitor the evolving laws and regulations in this area and take all reasonable measures to mitigate compliance risks, we cannot guarantee that our business and operations will not be adversely affected by the potential impact of the Revised CAC Measures, the Network Data Management Regulations or other laws and regulations related to privacy, data protection and information security.

Also, the National People's Congress released the Personal Information Protection Law, which became effective in 2021. The Personal Information Protection Law provides a comprehensive set of data privacy and protection requirements that apply to the processing of personal information and expands data protection compliance obligations to cover the processing of personal information of persons by organizations and individuals in China, and the processing of personal information of persons in China outside of China if such processing is for purposes of providing products and services to, or analyzing and evaluating the behavior of, persons in China. The Personal Information Protection Law also provides that critical information infrastructure operators and personal information processing entities who process personal information meeting a volume threshold set by Chinese cyberspace regulators are also required to store in China personal information generated or collected in China, and to pass a security assessment administered by Chinese cyberspace regulators for any export of such personal information. Lastly, the Personal

Information Protection Law contains proposals for significant fines for serious violations of up to RMB 50 million or 5% of annual revenues from the prior year and may also be ordered to suspend any related activity by competent authorities. We do not maintain, nor do we intend to maintain in the future, personally identifiable health information of patients in China.

In addition, certain industry-specific laws and regulations affect the collection and transfer of data in the PRC. The Regulations on the Administration of Human Genetic Resources of the PRC (the "HGR Regulation"), promulgated by the State Council, came into effect in 2019. It stipulates that foreign organizations, individuals, and the entities established or actually controlled by foreign organizations or individuals are forbidden to collect, preserve and export China's human genetic resources. Foreign organizations and the entities established or actually controlled by foreign organizations or individuals may only utilize and be provided with China's human genetic resources after satisfaction of all requirements under the HGR Regulation and other applicable laws, such as (i) China's human genetic resources being utilized only in international cooperation with Chinese scientific research institutions, universities, medical institutions, and enterprises for scientific research and clinical trials after completion of requisite approval or filing formalities with competent governmental authorities, and (ii) China's human genetic resources information being provided after required filing and information backup procedures have been gone through. In 2020, the SCNPC promulgated the Biosecurity Law of the PRC, which reaffirms the regulatory requirements stipulated by the HGR Regulation while potentially increasing the administrative sanctions where China's human genetic resources are collected, preserved, exported or used in international cooperation in violation of applicable laws. The Ministry of Science and Technology published the Implementing Rules for the Regulations on the Administration of Human Genetic Resources (the "HGR Implementing Rules"), which came into effect in 2023. The HGR Implementing Rules have, among other things, further clarified the scope of China's human genetic resources information, improved the procedure rules for applicable approval, filing and security review, and refined the provisions with respect to the forbiddance on the collection, preservation and export of China's human genetic resources by foreign organizations, individuals, and the entities established or actually controlled by foreign organizations or individuals. There remain significant uncertainties as to how various provisions of the HGR Regulation and the related laws and regulations may be interpreted and implemented. Given such uncertainty, although we have made great efforts to comply with mandatory requirements of laws and government authorities in this regard, we cannot assure you that we will be deemed at all times in full compliance with the HGR Regulation, the Biosecurity Law of the PRC, the HGR Implementing Rules and other applicable laws in our utilizing of and dealing with China's human genetic resources. As a result, we may be exposed to compliance risks under the HGR Regulation, the Biosecurity Law of the PRC and the HGR Implementing Rules.

Interpretation, application and enforcement of these laws, rules and regulations evolve from time to time and their scope may continually change, through new legislation, amendments to existing legislation or changes in enforcement. Compliance with China's Cyber Security Law, Data Security Law and Personal Information Protection Law could significantly increase the cost to us of providing our service offerings, require significant changes to our operations or even prevent us from providing certain service offerings in jurisdictions in which we currently operate or in which we may operate in the future. Despite our efforts to comply with applicable laws, regulations and other obligations relating to privacy, data protection and information security, it is possible that our practices, offerings or platform could fail to meet all of the requirements imposed on us by the Cyber Security Law, the Data Security Law, the Personal Information Protection Law and/or related implementing regulations. Any failure on our part to comply with such law or regulations or any other obligations relating to privacy, data protection or information security, or any compromise of security that results in unauthorized access, use or release of personally identifiable information or other data, or the perception or allegation that any of the foregoing types of failure or compromise has occurred, could damage our reputation, discourage new and existing counterparties from contracting with us or result in investigations, fines, suspension or other penalties by Chinese government authorities and private claims or litigation, any of which could adversely affect our business, financial condition and results of operations. Even if our practices are not subject to legal challenge, the perception of privacy concerns, whether or not valid, may harm our reputation and brand and adversely affect our business, financial condition and results of operations. Moreover, the legal uncertainty created by the Data Security Law, the Revised CAC Measures and the recent Chinese government actions could adversely affect our ability, on favorable terms, to raise capital, including engaging in follow-on offerings of our securities in the U.S. market.

Pharmaceutical companies operating in China are required to comply with extensive regulations and hold a number of permits and licenses to carry on their business. Our ability to obtain and maintain these regulatory approvals is uncertain, and future government regulation may place additional burdens on our current and planned operations in China.

The pharmaceutical industry in China is subject to extensive government regulation and supervision. The regulatory framework addresses all aspects of operating in the pharmaceutical industry, including product development activities, clinical trials, registration, production, distribution, packaging, labeling, storage and shipment, advertising, licensing and post-approval pharmacovigilance certification requirements and procedures, periodic renewal and reassessment processes, data security and data privacy protection requirements and compliance and environmental protection. In particular, we are subject to many of these laws and regulations because our wholly-owned subsidiary, AnHeart Therapeutics (Hangzhou) Co., Ltd., is the Marketing Authorization Holder ("MAH") for taletrectinib in China, and conducts research, development, and assists Innovent with certain commercialization activities in China. Violation of applicable laws and regulations may materially and adversely affect our business. The regulatory framework governing the pharmaceutical industry in China is subject to change and amendment from time to time. Any such change or amendment could materially and adversely impact our business, financial condition and prospects. The Chinese government has introduced various reforms to the Chinese healthcare system in recent years and may continue to do so, with an overall objective to expand basic medical insurance coverage and improve the quality and reliability of healthcare services. The specific regulatory changes under the various reform initiatives remain uncertain. The implementing measures to be issued may not be sufficiently effective to achieve the stated goals, and as a result, we may not be able to benefit from such reform to the extent we expect, if at all. Moreover, the various reform initiatives could give rise to regulatory developments, such as more burdensome administrative procedures, which may have an adverse effect on our business and prospects.

As a company with operations and business relationships outside of the United States, our business is subject to economic, political, regulatory and other risks associated with international operations.

As a company with operations in China, our business is subject to risks associated with conducting business outside the United States. In addition to our activities conducted by AnHeart Therapeutics (Hangzhou) Co., Ltd. in China, some of our suppliers and clinical trial relationships are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- differing and changing regulatory requirements for product approvals;
- differing jurisdictions could present different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates of the RMB;
- increasing geopolitical tensions between the U.S. and China and changes in a specific country's or region's political or economic environment especially with respect to a particular country's treatment of or stance towards other countries;
- trade protection measures, import or export licensing requirements or other restrictive actions by governments;
- differing reimbursement regimes and price controls in certain non-U.S. markets;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

- different tax treatment in various jurisdictions of options granted under our equity incentive plans;
- workforce uncertainty in countries where labor unrest is more common than in the United States; and
- business interruptions resulting from geo-political actions, including war and terrorism, health epidemics, or natural disasters including earthquakes, typhoons, floods and fires.

If we fail to comply with Chinese 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, fire safety and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Despite our efforts to comply fully with environmental and safety regulations, any violation of these regulations may result in substantial fines, criminal sanctions, revocations of operating permits, the shutdown of our facilities and the incurrence of obligations to take corrective measures.

Although we maintain workers' compensation insurance to cover costs and expenses incurred due to on-the-job injuries to our employees and public liability insurance to cover costs and expenses that may be incurred if third parties are injured on our property, such insurance may not provide adequate coverage against potential liabilities. Furthermore, the Chinese government may take steps towards the adoption of more stringent environmental regulations, and, due to the possibility of unanticipated regulatory or other developments, the amount and timing of future environmental expenditures may vary substantially from those currently anticipated. If there is any unanticipated change in the environmental regulations, our third-party manufacturers and other service providers may incur substantial capital expenditures to install, replace, upgrade or supplement their manufacturing facilities and equipment or make operational changes to limit any adverse impact or potential adverse impact on the environment in order to comply with new environmental protection laws and regulations. If such costs become prohibitively expensive, we may be forced to cease certain aspects of our business operations and our business may be materially adversely affected.

Development in the Chinese legal system could materially and adversely affect us.

Chinese laws and regulations govern our operations in China and the PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions under the civil law system may be cited for reference but have limited precedential value. As the laws and regulations are relatively new and the PRC legal system continues to evolve, there may be room for discretion in the implementation of these laws and regulations. And as these laws and regulations are evolving in response to changing economic and other conditions, factors related to the application and implementation of these laws and regulations may affect our business and results of operations.

We may be exposed to liabilities under the U.S. Foreign Corrupt Practices Act (the "FCPA"), and similar anti-corruption and anti-bribery laws of China and other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and any determination that we have violated these laws could have a material adverse effect on our business or our reputation.

Our operations are subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of China and other countries in which we operate. The FCPA and these other laws generally prohibit us, our officers, and our employees and intermediaries from, directly or indirectly, offering, authorizing or making improper payments to non-U.S. government officials for the purpose of obtaining or retaining business or other advantage. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. As our business expands, the applicability of the FCPA and other anti-bribery laws to our operations will increase. If our procedures and controls to monitor anti-bribery compliance fail to protect us from reckless or criminal acts committed by our employees or agents or if we, or our employees, agents, contractors or other collaborators, fail to comply with applicable anti-bribery laws, our reputation could be harmed and we could incur criminal or civil penalties, other sanctions and/or significant expenses,

which could have a material adverse effect on our business, including our financial condition, results of operations, cash flows and prospects.

In addition, our products may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international or domestic sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to, existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business.

Regulatory requirements on currency exchange may limit our ability to receive and use effectively financing in foreign currencies.

Our Chinese subsidiaries' ability to obtain currency exchange is subject to certain foreign exchange regulations and, in the case of transactions under the capital account, requires the approval of and/or registration with Chinese government authorities, including the State Administration of Foreign Exchange ("SAFE"). In particular, if we finance our Chinese subsidiaries by means of foreign debt from us or other foreign lenders, the amount is not allowed to, among other things, exceed the statutory limits and such loans must be registered with the local branch of SAFE. If we finance our Chinese subsidiaries by means of additional capital contributions, these capital contributions are subject to registration with the State Administration for Market Regulation or its local branch, reporting of foreign investment information with the Ministry of Commerce of the People's Republic of China ("MOFCOM"), or its local branch or registration with other governmental authorities in China.

In light of the various requirements imposed by Chinese regulations on loans to, and direct investment in, China-based entities by offshore holding companies, we cannot assure you that we will be able to complete the necessary government requirements or obtain the necessary government approvals on a timely basis, if at all, with respect to future loans or capital contributions by us to our Chinese subsidiaries. If we fail to adhere to such requirements or obtain such approval, our ability to fund our Chinese operations, including research and development activities through AnHeart Therapeutics (Hangzhou) Co., Ltd., may be negatively affected, which could materially and adversely affect our ability to fund and expand our business.

Chinese regulations relating to the establishment of offshore special purpose companies by residents in China may subject our China resident beneficial owners or our wholly foreign-owned subsidiaries in China to liability or penalties, limit our ability to inject capital into these subsidiaries, limit these subsidiaries' ability to increase their registered capital or distribute profits to us, or may otherwise adversely affect us.

In 2014, SAFE promulgated the SAFE Circular 37, which requires residents of China to register with local branches of SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with such residents' legally owned assets or equity interests in domestic enterprises or offshore assets or interests, referred to in SAFE Circular 37 as a "special purpose vehicle." The term "control" under SAFE Circular 37 is broadly defined as the operation rights, beneficiary rights or decision-making rights acquired by residents of China in the offshore special purpose vehicles or Chinese companies by such means as acquisition, trust, proxy, voting rights, repurchase, convertible bonds or other arrangements. SAFE Circular 37 further requires amendment to the registration in the event of any changes with respect to the basic information of or any significant changes with respect to the special purpose vehicle, such as an increase or decrease of capital contributed by China residents, share transfer or exchange, merger, division or other material events. If the shareholders of the offshore holding company who are residents of China do not complete their registration with the local SAFE branches, the Chinese subsidiaries may be prohibited from making distributions of profits and proceeds from any reduction in capital, share transfer or liquidation to the offshore parent company and from carrying out subsequent cross-border foreign exchange activities, and the offshore parent company may be restricted in its ability to contribute additional capital into its Chinese subsidiaries. Moreover, failure to comply with the SAFE registration and amendment

requirements described above could result in liability under Chinese law for evasion of applicable foreign exchange restrictions.

Certain residents of China may hold direct or indirect interests in our company, and we will request residents of China who we know hold direct or indirect interests in our company, if any, to make the necessary applications, filings and amendments as required under SAFE Circular 37 and other related rules. However, we may not at all times be fully aware or informed of the identities of our shareholders or beneficial owners that are required to make such registrations, and we cannot provide any assurance that these residents will comply with our requests to make or obtain any applicable registrations or comply with other requirements under SAFE Circular 37 or other related rules. The failure or inability of our China resident shareholders to comply with the registration procedures set forth in these regulations may subject us to fines or legal sanctions, restrictions on our cross-border investment activities or those of our China subsidiaries and limitations on the ability of our wholly foreign-owned subsidiaries in China to distribute dividends or the proceeds from any reduction in capital, share transfer or liquidation to us, and we may also be prohibited from injecting additional capital into these subsidiaries. Moreover, failure to comply with the various foreign exchange registration requirements described above could result in liability under Chinese law for circumventing applicable foreign exchange restrictions. As a result, our business operations and our ability to make distributions to you could be materially and adversely affected.

We and our shareholders face uncertainties in China with respect to indirect transfers of equity interests in China resident enterprises.

The indirect transfer of equity interests in China resident enterprises by a non-China resident enterprise ("Indirect Transfer"), is potentially subject to income tax in China at a rate of 10% on the gain if such transfer is considered as not having a commercial purpose and is carried out for tax avoidance. The State Administration of Taxation ("SAT") has issued several rules and notices to tighten the scrutiny over acquisition transactions in recent years. The Announcement of the State Administration of Taxation on Several Issues Concerning the Enterprise Income Tax on Indirect Property Transfer by Non-Resident Enterprises ("SAT Circular 7"), sets out the scope of Indirect Transfers, which includes any changes in the shareholder's ownership of a foreign enterprise (excluding any China resident enterprise) holding Chinese Taxable Assets directly or indirectly in the course of a group's overseas restructuring, and the factors to be considered in determining whether an Indirect Transfer has a commercial purpose. The term "Chinese Taxable Assets" refers to the assets of a branch or establishment in China, real estate located within China, and equity interests of a China resident enterprise, among others, which are directly held by a non-China resident enterprise and for which the proceeds from its/their transfer are subject to income tax in China according to the relevant provisions of China's tax laws. An Indirect Transfer satisfying all the following criteria will be deemed to lack a bona fide commercial purpose and be taxable under Chinese laws: (i) 75% or more of the equity value of the foreign enterprise being transferred is derived directly or indirectly from the Chinese Taxable Assets; (ii) at any time during the one-year period before the indirect transfer, 90% or more of the total asset value of the foreign enterprise (excluding cash) is comprised directly or indirectly of investments in China, or during the one-year period before such Indirect Transfer, 90% or more of the foreign enterprise's income is derived directly or indirectly from China; (iii) the functions performed and risks assumed by the foreign enterprise and any of its subsidiaries that directly or indirectly hold the Chinese Taxable Assets are limited and are insufficient to prove their economic substance; and (iv) the non-Chinese tax payable on the gain derived from the indirect transfer of the Chinese Taxable Assets is lower than the potential Chinese income tax on the direct transfer of such Chinese Taxable Assets. A transaction that does not satisfy all four tests in the immediately preceding sentence may nevertheless be deemed to lack a bona fide commercial purpose if the taxpayer cannot justify such purpose from a totality approach, taking into account the transferred group's value, income, asset composition, the history and substance in the structure, the non-Chinese tax implications, any tax treaty benefit and the availability of alternative transactions. Nevertheless, a non-China resident enterprise's buying and selling shares of the same listed foreign enterprise on the public market will fall under the safe harbor available under SAT Circular 7 if the shares sold were purchased on the public market as well and will not be subject to Chinese tax pursuant to SAT Circular 7.

We face uncertainties regarding the reporting requirements for and impact on (i) future private equity financing transactions, share exchanges or other transactions involving the transfer of shares in our company by investors that are non-China resident enterprises, or (ii) the sale or purchase of shares of other non-China resident companies directly or indirectly holding Chinese Taxable Assets by us. For example, the Chinese tax authorities may consider that a future securities offering involves an indirect change of shareholding in our Chinese subsidiaries and therefore it may be regarded as an Indirect Transfer under SAT Circular 7. Even if we believe no SAT Circular 7 reporting is required

on the basis that such an offering has commercial purposes and is not conducted for tax avoidance, Chinese tax authorities may urge us to report under SAT Circular 7 and request that we and our Chinese subsidiaries assist with the filing. As a result, we and our Chinese subsidiaries may be required to spend significant resources to provide assistance and comply with SAT Circular 7, or to establish that we or our investors that are non-China resident enterprises should not be subject to tax under SAT Circular 7, for such an offering or other transactions, which may have an adverse effect on our and our Chinese subsidiaries' financial condition and day-to-day operations.

Any failure to comply with Chinese regulations regarding the registration requirements for our employee equity incentive plans may subject us to fines and other legal or administrative sanctions, which could adversely affect our business, financial condition and results of operations.

In 2012, the SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies (the "Stock Option Rules"). In accordance with the Stock Option Rules and other relevant rules and regulations, Chinese citizens or non-Chinese citizens residing in China for a continuous period of not less than one year who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with SAFE through a domestic qualified agent, which could be a Chinese subsidiary of such overseas listed company, and complete certain procedures. Our employees who are Chinese citizens or who reside in China for a continuous period of not less than one year and who participate in our stock incentive plans are subject to such regulation. We plan to assist our employees to register their equity awards. However, any failure of our Chinese individual beneficial owners and holders of equity awards to comply with the SAFE registration requirements may subject them to fines and legal sanctions and may limit the ability of our Chinese subsidiaries to distribute dividends to us. We also face regulatory uncertainties that could restrict our ability to adopt additional incentive plans for our employees under Chinese law.

Risks Related to Ownership of Our Securities

The market price of our securities may be volatile and fluctuate substantially, which could result in substantial losses for our investors and may subject us to securities litigation suits.

The market price of our securities may be volatile. The stock market in general and the market for pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their securities or above the price they paid. The market price for our securities may be influenced by many factors, including:

- lower than expected market acceptance of IBTROZI or our other product candidates if approved;
- adverse regulatory decisions;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- the impact of health epidemics;
- the commencement, enrollment or results of any future clinical trials we may conduct, or changes in the development status of our product candidates;
- adverse results from, delays in or termination of clinical trials;
- unanticipated serious safety concerns related to the use of our product candidates;
- changes in financial estimates by us or by any securities analysts who might cover our securities;
- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the pharmaceutical industry;

- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our securities;
- disputes or other developments relating to intellectual property rights, including patents, litigation matters and our ability to obtain, maintain, defend, protect and enforce patent and other intellectual property rights for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- proposed changes to healthcare laws in the U.S., China or other foreign jurisdictions, or speculation regarding such changes including changes in the structure of healthcare payment systems;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

The dual-class structure of our common stock has the effect of concentrating voting power with our Chief Executive Officer, which limits other stockholders' ability to influence the outcome of important transactions, including a change in control.

Dr. Hung holds all of the outstanding shares of our Class B Common Stock and approximately 17% of our Class A and Class B Common Stock outstanding. In addition to voting together with the Class A Common Stock (with one vote per share) on all matters, the holders of Class B Common Stock have (i) the right to elect and remove without cause three of our directors plus at least 50% of all directors in excess of seven and (ii) an approval right over any acquisition (whether by merger, sale of shares or sale of assets) or our liquidation. Accordingly, Dr. Hung has the ability to control or exert substantial influence over all matters submitted to our stockholders for approval, including the election of directors and amendments of our organizational documents, and an approval right over any acquisition or liquidation of our company. Dr. Hung may have interests that differ from those of the other stockholders and may vote in a way with which the other stockholders disagree and which may be adverse to their interests. This concentrated control may have the effect of delaying, preventing or deterring a change in control, could deprive our stockholders of an opportunity to receive a premium for their capital stock as part of a sale of our company, and might ultimately affect the market price of shares of our Class A Common Stock.

We cannot predict the impact our dual-class structure may have on the market price of our Class A common stock.

We cannot predict whether our dual-class structure, combined with the concentrated voting power of Dr. Hung by virtue of his ownership of 100% of the outstanding shares of our Class B Common Stock, will result in a lower or more volatile market price of our Class A Common Stock in the future, or in adverse publicity or other adverse consequences. Certain index providers have announced restrictions on including companies with multi-class share structures in certain of their indices. For example, in 2017, FTSE Russell and Standard & Poor's announced that they would cease to allow most newly public companies utilizing dual or multi-class capital structures to be included in their indices. Under the announced policies, our dual-class capital structure makes us ineligible for inclusion in any of these indices. Given the sustained flow of investment funds into passive strategies that seek to track certain indices, exclusion from stock indices would likely preclude investment by many of these funds and could make our securities

less attractive to other investors. As a result, the market price of our Class A Common Stock could be adversely affected.

There can be no assurance that we will be able to comply with the continued listing standards of the NYSE.

Our Class A Common Stock is listed on the NYSE under the symbol "NUVB". Our continued eligibility for listing will depend on our compliance with the continued listing standards of the NYSE and may depend on the number of our shares that are redeemed. If the NYSE delists our securities from trading on its exchange for failure to meet the listing standards, we and our stockholders could face significant negative consequences including:

- limited availability of market quotations for our securities;
- a determination that our Common Stock is a "penny stock" which will require brokers trading in our Common Stock to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for shares of our Common Stock;
- a limited amount of analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

Future sales, or the perception of future sales, by us or our stockholders in the public market could cause the market price for our securities to decline.

The sale of our securities in the public market, or the perception that such sales could occur, could harm the prevailing market price of our securities. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

Immediately prior to our acquisition of AnHeart, we had a total of approximately 219,083,219 shares of Common Stock outstanding, consisting of approximately 218,083,219 shares of Class A Common Stock and 1,000,000 shares of Class B Common Stock. All of these shares are freely tradable without registration under the Securities Act, and without restriction by persons other than our "affiliates" (as defined under Rule 144 of the Securities Act, "Rule 144"), including our directors, executive officers and other affiliates.

On September 3, 2024, we held our 2024 Annual Meeting of Stockholders at which our stockholders approved for the purpose of complying with the listing rules of the New York Stock Exchange, the issuance of up to 85,120,200 shares of Class A Common Stock upon conversion of Series A Non-Voting Convertible Preferred Stock issued in April 2024. The conversion of the Convertible Preferred Stock into 85,120,200 shares of Class A Common Stock was completed and those shares were issued and outstanding as of September 30, 2024.

In addition, the shares of Class A Common Stock reserved for future issuance under our equity incentive plans will become eligible for sale in the public market once those shares are issued, subject to provisions relating to various vesting agreements, lock-up agreements and, in some cases, limitations on volume and manner of sale applicable to affiliates under Rule 144, as applicable. Our compensation committee of our board of directors may determine the exact number of shares to be reserved for future issuance under our equity incentive plans at its discretion. We have filed and expect to file registration statements on Form S-8 under the Securities Act to register shares of Class A Common Stock or securities convertible into or exchangeable for shares of Class A Common Stock issued pursuant to our equity incentive plans. Any such Form S-8 registration statements will automatically become effective upon filing. Accordingly, shares registered under such registration statements will be available for sale in the open market.

In the future, we may also issue our securities in connection with investments or acquisitions. The amount of shares of Class A Common Stock issued in connection with an investment or acquisition could constitute a material portion of our then-outstanding shares of Class A Common Stock. Any issuance of additional securities in connection with investments or acquisitions may result in additional dilution to our stockholders.

Because we do not anticipate paying any cash dividends on our Class A common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.

We may retain future earnings, if any, for future operations, expansion and debt repayment and have no current plans to pay any cash dividends for the foreseeable future. Any decision to declare and pay dividends as a public company in the future will be made at the discretion of our board of directors and will depend on, among other things, our results of operations, financial condition, cash requirements, contractual restrictions and other factors that our

board of directors may deem relevant. In addition, our ability to pay dividends may be limited by covenants of any existing and future outstanding indebtedness we or our subsidiaries incur. As a result, you may not receive any return on an investment in our securities unless you sell your securities for a price greater than that which you paid for it.

We may issue additional securities without your approval, which would dilute your ownership interests and may depress the market price of our securities.

As of December 31, 2025, we have options outstanding to purchase approximately 73,963,104 shares of Class A Common Stock. Pursuant to the 2021 Equity Incentive Plan (the "2021 Plan") and the Employee Stock Purchase Plan (the "2021 ESPP"), we may issue under the 2021 Plan an aggregate of up to 42,744,648 shares of Class A Common Stock and Class B Common Stock, which amount will be subject to increase from time to time. In addition, in the AnHeart acquisition, we assumed the AnHeart equity incentive plans and reserved an aggregate of approximately 15,943,933 shares of Class A Common Stock for issuance upon exercise of outstanding options or settlement of outstanding restricted stock units issued under those plans. We may also issue additional shares of Class A Common Stock or other equity securities of equal or senior rank in the future in connection with, among other things, future acquisitions or repayment of outstanding indebtedness, without stockholder approval, in a number of circumstances.

The issuance of additional shares or other equity securities of equal or senior rank would have the following effects:

- existing stockholders' proportionate ownership interest in our company will decrease;
- the amount of cash available per share, including for payment of dividends in the future, may decrease;
- the relative voting strength of each previously outstanding common stock may be diminished; and
- the market price of our securities may decline.

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

Our amended and restated certificate of incorporation contains provisions that may delay or prevent an acquisition of the company or change in our management in addition to the significant rights of Dr. Hung as the holder of 100% of the outstanding shares of our Class B Common Stock. These provisions may make it more difficult for stockholders to replace or remove members of our board of directors. Because the board of directors is responsible for appointing the members of the management team, these provisions could in turn frustrate or prevent any attempt by our stockholders to replace or remove our current management. In addition, these provisions could limit the price that investors might be willing to pay in the future for shares of our Class A Common Stock. Among other things, these provisions include:

- the limitation of the liability of, and the indemnification of, our directors and officers;
- a prohibition on actions by our stockholders except at an annual or special meeting of stockholders;
- a prohibition on actions by our stockholders by written consent; and
- the ability of the board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by the board of directors.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the "DGCL"), which prohibits a person who owns 15% or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired 15% or more of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. This could discourage, delay or prevent a third party from acquiring or merging with us, whether or not it is desired by, or beneficial to, our stockholders. This could also have the effect of discouraging others from making tender offers for our Class A Common Stock, including transactions that may be in our stockholders' best interests. Finally, these provisions establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings. These provisions would apply even if the offer may be considered beneficial by some stockholders.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America are the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising under the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine or otherwise related to our internal affairs.

To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could harm our business.

We are eligible to report as a "smaller reporting company," and as a result of the reduced reporting requirements applicable to "smaller reporting companies," our securities may be less attractive to investors.

We are eligible to report as a smaller reporting company. For as long as we continue to be eligible to report as a "smaller reporting company," we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "smaller reporting companies," including exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. If some investors find our securities less attractive because we rely on any of these exemptions, there may be a less active trading market for our securities and the price of our securities may be more volatile.

General Risk Factors

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the NYSE. Section 302 of the Sarbanes-Oxley Act requires, among other things, that public companies report on the effectiveness of our disclosure controls and procedures in our quarterly and annual reports and, beginning with this report, Section 404 of the Sarbanes-Oxley Act requires that we perform system and process evaluation and testing of our internal control over financial reporting to

allow management to report on the effectiveness of our internal control over financial reporting in our Annual Report on Form 10-K for that year. This has required us to incur substantial additional professional fees and internal costs to expand our accounting and finance functions and to expend significant management efforts.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the NYSE, the SEC or other regulatory authorities. In addition, our securities may not be able to remain listed on the NYSE or any other securities exchange.

We will incur costs and demands upon our management as a result of complying with the laws and regulations affecting public companies in the U.S., which may harm our business.

As a public company listed in the U.S., we incur on an ongoing basis significant legal, accounting and other expenses. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and the NYSE may increase legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from regular business activities to compliance activities. If, notwithstanding our efforts, we fail to comply with new laws, regulations and standards, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain certain types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

If securities or industry analysts cease publishing research or reports about us, our business or our market, or if they change their recommendations regarding our securities adversely, the price and trading volume of our securities could decline.

Equity research analysts may cease providing research coverage of our securities at any time, and such lack of research coverage may adversely affect the market price of our securities. In any event, we do not have any control over the analysts or the content and opinions included in their reports and the price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our securities' prices or trading volume to decline.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity

We have implemented and maintain various information security processes designed to identify, assess, and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property and confidential information that is proprietary, strategic or competitive in nature.

Our audit committee of our board of directors, together with our information security function and third-party service providers help identify, assess, and manage the Company's cybersecurity threats and risks. We take steps designed to identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment and the Company's risk profile using various methods including, for example using automated tools, subscribing to reports and services that identify cybersecurity threats, analyzing reports of threats and actors, conducting scans of the threat environment, evaluating our and our industry's risk profile, evaluating threats reported to us, conducting internal

and/or external audits, conducting threat assessments for internal and external threats, third party threat assessments, conducting vulnerability assessments to identify vulnerabilities, and using external intelligence feeds.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: cybersecurity-related policies and procedures (including incident response plans and policies, a vulnerability management policy, disaster recovery/business continuity plans), incident detection and response, periodic risk assessments, implementation of security standards/certifications, encryption of data, network security and system monitoring controls (including technology solutions such as antivirus, firewalls and monitoring tools), awareness training for all employees, security measures, asset management, tracking and disposal, penetration testing, cybersecurity insurance coverage, and a dedicated cybersecurity staff.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, (1) cybersecurity risk is addressed as a component of the Company's enterprise risk management program; (2) security management works with management to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business; (3) our management evaluates material risks from cybersecurity threats against our overall business objectives and reports to the audit committee of the board of directors, which evaluates our overall enterprise risk, and (4) we have a cybersecurity incident response plan to identify, assess, respond to, and inform escalating levels of management based on the nature and severity of such incidents.

We use third-party service providers to assist us from time to time in an effort to identify, assess, and manage material risks from cybersecurity threats, including for example professional services firms, including legal counsel, threat intelligence service providers, cybersecurity consultants, cybersecurity software providers, managed cybersecurity service providers (including SIEM tools and 24/7 managed detection and response), penetration testing firms, and dark web monitoring services.

We use third-party service providers to perform a variety of functions throughout our business, such as application providers, hosting companies, and contract research organizations. We have a vendor management program designed to manage cybersecurity risks associated with our use of these providers. The program includes the following elements such as a risk assessment, a security questionnaire, a review of the vendor's written security program, a review of security assessments and other reports. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see the section titled "Risk Factors" in Item 1A of this Annual Report on Form 10-K, including the risk factor titled "*—If our information technology systems or those of third parties with whom we work, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences*."

Governance

Our board of directors addresses the Company's cybersecurity risk management as part of its general oversight function. The audit committee of our board of directors is responsible for oversight of the Company's cybersecurity risk. Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, including our Senior Director Infrastructure, Operations and Cyber Security who has fifteen years of experience in the industry and oversees the Company's infrastructure, operations and cyber security, and our Vice President of Legal, who has expertise in legal, compliance and privacy matters.

Our Senior Director Infrastructure, Operations and Cyber Security is responsible for integrating cybersecurity risk considerations into the Company's overall risk management strategy, communicating key priorities to relevant personnel, approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, reviewing security assessments and other security-related reports, and retaining assessors, consultants, auditors, or third parties in connection with the company's cybersecurity program.

Our cybersecurity incident response processes and policies are designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including the Senior Director Infrastructure,

Operations and Cyber Security, who works with the Company's incident response team to help the Company mitigate and remediate cybersecurity incidents of which they are notified. In addition, the Company's incident response processes and policies include reporting to the audit committee of the board of directors for certain cybersecurity incidents.

The board of directors and audit committee receive periodic reports concerning the Company's significant cybersecurity threats and risk and the processes the Company has implemented to address them. The board of directors and audit committee also has access to various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

Item 2. Properties.

Our principal executive offices are located in New York, New York, where we lease approximately 7,900 square feet of office space under a lease that terminates in 2027, and in San Francisco, where we lease approximately 19,418 square feet of office space that terminates in 2029. In the second half of 2026, we plan to move our New York office to a new location in New York, New York with approximately 18,563 square feet of office space and a lease expiring in 2037. We also occupy office space located in Burlington, Massachusetts, where we lease approximately 2,235 square feet of office space under a lease that terminates in 2027, as well as a total of approximately 1,799 square meters of office space in the People's Republic of China, in the cities of Beijing, Guangzhou, Hangzhou and Shanghai, under leases that terminate in 2026 through 2029.

We consider our current office spaces adequate to meet our ongoing needs. From time to time we may evaluate additional or substitute office spaces. We believe that we will be able to obtain additional facilities, as needed, on commercially reasonable terms.

Item 3. Legal Proceedings.

On July 30, 2025, Tim Patterson filed a derivative complaint (Tim Patterson, derivatively on behalf of Nuvation Bio, Inc. v. David Hung, et al. Index No. 654535/2025) (the "Action") in the Supreme Court of the State of New York for the County of New York on behalf of Nuvation Bio against our seven current directors and one former director (the "Individual Defendants"). The Action asserts claims against the Individual Defendants for allegedly breaching their fiduciary duties to us by awarding our directors excessive compensation between 2021 and 2024 and seeks restitution from the Individual Defendants, changes to our director compensation policies and practices, and attorneys' fees and other costs of suit. On November 12, 2025, the plaintiff voluntarily discontinued the Action without prejudice.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

On February 10, 2021, Panacea and Legacy Nuvation Bio completed the Merger. Following the Merger, we changed the name of the combined company to Nuvation Bio Inc.

Our Class A common stock and warrants to purchase Class A common stock originally began trading as units on The New York Stock Exchange on July 1, 2020. Prior to July 1, 2020, there was no public market for our securities. Following the Merger, beginning February 11, 2021, our Class A common stock and warrants to purchase Class A common stock continued trading on The New York Stock Exchange under the symbols "NUVB" and "NUVB.WS," respectively. On February 10, 2026, the warrants to purchase Class A Common Stock expired and were delisted pursuant to a Form 25 filed by The New York Stock Exchange.

Holders of Record

As of February 26, 2026, there were approximately 36 holders of record of our Class A common stock.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors.

Recent Sales of Unregistered Equity Securities

None

Issuer Purchases of Equity Securities

None

Item 6. Reserved

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

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Exchange Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Forward-looking statements are identified by words such as "believe," "will," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "could," "potentially" or the negative of these terms or similar expressions. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this report in Part I, Item 1A — "Risk Factors," and elsewhere in this report. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments. We caution investors that our business and financial performance are subject to substantial risks and uncertainties. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this Annual Report on Form 10-K. While we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into or review of, all relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely on these statements.

Overview

We are a commercial-stage, global biopharmaceutical company focused on tackling some of the greatest challenges in cancer treatment by developing differentiated and novel product candidates. We were founded in 2018 by our chief executive officer, David Hung, M.D., who founded Medivation, Inc. and led its successful development of oncology drugs Xtandi® and talazoparib (now marketed as Talzenna®), leading to its $14.3 billion sale to Pfizer Inc. ("Pfizer") in 2016. We leverage our team's extensive expertise in medicinal chemistry, preclinical development, drug development, business development, manufacturing, and commercialization to pursue oncology targets validated by strong clinical or preclinical data and develop novel small molecules that improve the activity and overcome the liabilities of currently marketed drugs.

We commercially launched IBTROZI in the U.S. in June 2025, following its approval by the FDA on June 11, 2025 for the treatment of adult patients with locally advanced or metastatic ROS1+ NSCLC. Taletrectinib has also been approved by Japan's MHLW and by China's NMPA for the treatment of adult patients with locally advanced or metastatic ROS1+ NSCLC. Taletrectinib is being commercialized in Japan by our partner NK under the brand name IBTROZI and in China by our partner Innovent under the brand name DOVBLERON®. Taletrectinib has been granted Orphan Drug Designation by the U.S. FDA for the treatment of patients with ROS1+ NSCLC and other NSCLC indications, and was previously granted Breakthrough Therapy Designations by both the U.S. FDA and China's

NMPA for the treatment of both TKI-naïve and TKI-pretreated disease patients with locally advanced or metastatic ROS1+ NSCLC.

Taletrectinib continues to be evaluated for the treatment of patients with locally advanced or metastatic ROS1+ NSCLC in two Phase 2 single-arm pivotal studies: TRUST-I in China, and TRUST-II, a global study, as well as in a confirmatory randomized Phase 3 study versus crizotinib in China known as TRUST-III. Taletrectinib is also being evaluated for the adjuvant treatment of patients with resected ROS1+ early-stage NSCLC in a global Phase 3, placebo-controlled study known as TRUST-IV.

In addition to taletrectinib, our clinical stage pipeline includes safusidenib, a novel, oral, potent, brain penetrant, targeted inhibitor of mutant isocitrate dehydrogenase 1 ("mIDH1"). Safusidenib is being evaluated in the SIGMA study, which is currently a randomized registration-enabling phase 3 study evaluating the efficacy and safety of safusidenib versus placebo for the maintenance treatment of patients with high-risk or high-grade IDH1-mutant astrocytoma following standard-of-care.

Recent Developments

- On November 8, 2025, positive results from a Phase 2 study of safusidenib in Japanese patients with chemotherapy- and radiotherapy-naïve grade 2 IDH1-mutant gliomas were published in the online journal of *Neuro-Oncology*.
- In January 2026, we announced entry into an exclusive license agreement for taletrectinib in Europe and additional countries with Eisai.
- On February 10, 2026, the outstanding warrants to purchase Class A Common stock expired and were delisted pursuant to a Form 25 filed by The New York Stock Exchange.

Financial Overview

Since our inception in 2018, we have focused substantially all of our resources on conducting research and development activities, including drug discovery, preclinical studies, clinical trials, establishing and maintaining our intellectual property portfolio, developing our manufacturing network and managing the manufacture of clinical and research material, hiring personnel, raising capital and providing general and administrative support for these operations. Our revenue related to its out-licensing collaborative agreements consists of product revenue, upfront license fees and milestone payments, royalty revenue and research and development services revenue from its collaboration agreements. We have funded our operations to date primarily from the issuance and sale of our common and preferred stock, including through the Merger and a Private Investment in Public Equity ("PIPE") financing in connection with the Merger.

We have incurred net losses in each year since inception. As of December 31, 2025, we had an accumulated deficit of $1,115.4 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations as well as a charge related to the acquisition of an in-process research and development asset. We expect to continue to incur significant expenses and increasing operating losses over at least the next several years. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- advance product candidates through clinical trials;
- pursue regulatory approval of product candidates;
- operate as a public company;
- continue our preclinical programs and clinical development efforts;
- continue research activities for the discovery of new product candidates; and
- manufacture supplies for our preclinical studies and clinical trials.

In addition, we expect to incur additional costs associated with operating as a public company, including significant legal, audit, accounting, regulatory, tax-related, director and officer insurance, investor relations and other expenses that we did not incur as a private company. As a result, we will need substantial additional funding to support

our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the public or private sale of equity, government or private party grants, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. If we are unable to obtain additional funding, we could be forced to delay, reduce or eliminate some or all of our research and development programs, product portfolio expansion or any commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations. If we raise funds through strategic collaborations or other similar arrangements with third parties, we may have to relinquish valuable rights to our platform technology, future revenue streams, research programs or product candidates or may have to grant licenses on terms that may not be favorable to us and/or may reduce the value of our Common Stock. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide. Because of the numerous risks and uncertainties associated with product development, we cannot predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability.

On March 3, 2025, we announced the closing of a non-dilutive financing of up to $250.0 million from Sagard. The financing is comprised of a $150.0 million synthetic royalty financing and a $100.0 million senior secured term loan. The $150 million from the synthetic royalty financing and the first $50.0 million tranche of the term loan was funded on June 25, 2025 upon FDA's approval of IBTROZI. The transaction will support the U.S. launch of IBTROZI and general corporate purposes.

Components of Results of Operations

Revenues

Prior to our commercialization of IBTROZI, substantially all of our revenues were generated from payments under prior collaboration agreements, and milestones, royalties and other revenues from our licensing arrangements. To date, these collaborative arrangements have included out-licenses of and options to out-licensing in-licensed compounds to other parties. These arrangements may include non-refundable upfront payments, contingent obligations for potential development, regulatory and commercial performance milestone payments, cost reimbursement arrangements and royalty payments. Our revenue related to our out-licensing collaborative agreements consists of product revenue, upfront license fees, milestone payments, royalty revenue and research and development services revenue from its collaboration agreements.

We receive payments from our customers based on billing terms established in the contract. Up-front payments and fees are recorded as contract liabilities (e.g., deferred revenue) upon receipt or when due until we perform our obligations under the arrangement. In the event of an early termination of a collaboration agreement, any contract liabilities would be recognized in the period in which all our obligations under the agreement have been fulfilled.

Cost of Sales

Cost of sales includes primarily of all product related costs, third-party manufacturing, distribution, employee personnel costs and amortization of our licensed market approval for IBTROZI.

Cost of Collaboration and License Agreements Revenue

Cost of collaboration and license agreements revenue includes royalties on net sales of IBTROZI owed to our licensing partner and the proportion of expense recognized under the terms of our collaboration agreements.

Research and Development Expenses

Research and development expenses include:

- expenses incurred under agreements with third-party contract organizations, and consultants;
- costs related to production of drug substance, including fees paid to contract manufacturers;
- laboratory and vendor expenses related to the execution of preclinical trials; and
- employee-related expenses, which include salaries, benefits and stock-based compensation.

We expense all research and development costs in the periods in which they are incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks and estimates of services performed using information and data provided to us by our vendors and third-party service providers. Nonrefundable advance payments for goods or services to be received in future periods for use in research and development activities are deferred and capitalized. The capitalized amounts are then expensed as the related goods are delivered and as services are performed. We expense in-process research and development projects acquired as part of asset acquisitions that have no alternative future use.

We expect our research and development expenses to increase for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, as our product candidates advance into later stages of development, and as we begin to conduct clinical trials. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist of personnel-related costs, facilities costs, depreciation and amortization expenses and professional services expenses, including legal, human resources, audit and accounting services. Personnel-related costs consist of salaries, benefits and stock-based compensation. Facilities costs consist of rent and maintenance of facilities. We anticipate increased expenses related to compliance with the rules and regulations of the SEC, NYSE, insurance premiums, investor relations activities and other administrative and professional services.

Other Income (Expense), Net

Other income (expense) consists of change in fair value of warrant liabilities, interest earned on our cash equivalents and investments, interest expense, advisory expense related to our investments and realized gains and losses on marketable securities.

Results of Operations for the Years Ended December 31, 2025 and 2024

Revenues

The following table summarizes total revenue recognized for the years ended December 31, 2025 and 2024:

	For the Years Ended December 31,	
	2025	2024
Revenues:		
Product revenue, net	$ 24,663	$ —
Collaboration and license agreements revenue	38,239	7,873
Total revenues	$ 62,902	$ 7,873

Product Revenue, Net

On June 11, 2025, we announced that the FDA approved IBTROZI for the treatment of adult patients with locally advanced or metastatic ROS1+ non-small cell lung cancer (“NSCLC”). To date, our only source of product revenue has been from the U.S. sales of IBTROZI. We began shipping IBTROZI to our U.S. customers in June 2025. Net product revenue from U.S. sales of IBTROZI was approximately $24.7 million for the year ended December 31, 2025.

Collaboration and License Agreements Revenue

Collaboration and license agreements revenue increased by $30.3 million for the year ended December 31, 2025 compared to 2024. The increase is primarily due to a $19.1 million increase in license revenue and a $6.3 million increase in research and development service revenue as a result of the milestone payment from Nippon Kayaku for

the establishment of the reimbursement price in Japan in December 2025, a $1.3 million increase in royalty revenue, and a $3.6 million increase in product supply.

Costs and Expenses

The following table presents a breakdown of our costs and expenses by functional category:

	Years Ended December 31,		Increase /
	2025	2024	(Decrease)
(In thousands)			
Costs and expenses:			
Cost of sales	$ 856	$ —	$ 856
Cost of collaboration and license agreements revenue	8,442	7,078	1,364
Research and development	115,106	99,119	15,987
Acquired in-process research and development	—	425,070	(425,070)
Selling, general and administrative	151,562	69,233	82,329
Total costs and expenses	$ 275,966	$ 600,500	$ (324,534)

Cost of Sales

Cost of sales increased by $0.9 million for the year ended December 31, 2025 was primarily due to amortization of our licensed market approval. During the year ended December 31, 2024, there were no cost of sales recognized.

Cost of Collaboration and License Agreements Revenue

Cost of collaboration and license agreements revenue increased by $1.4 million for the year ended December 31, 2025 compared to 2024. The increase was primarily due to a $2.7 million increase in royalty payment for Daiichi Sankyo offset by $1.3 million decrease in research and development service costs under the term of our collaboration agreement with Innovent.

Research and Development Expenses

Research and development expenses increased by $16.0 million for the year ended December 31, 2025 compared to 2024. The increase was primarily due to a $7.8 million increase in salaries and other benefits driven by the increase in headcount and stock-based compensation primarily related to one-time charge for the vesting of performance-based awards upon receiving U.S. FDA approval of taletrectinib, a $12.1 million increase in third-party costs related to clinical studies, and a $0.1 million increase in amortization of assembled workforce offset by a $4.0 million decrease in regulatory milestone payments to Daiichi.

Acquired In-process Research and Development Expenses

On April 9, 2024, as a result of the acquisition of AnHeart, we recorded a $425.1 million charge representing an acquired in-process research and development asset with no alternative future use in acquired in-process research and development expenses.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $82.3 million for the year ended December 31, 2025, compared to 2024. The increase was due to a $39.4 million increase in personnel-related costs as a result of the increase in headcount and stock-based compensation primarily related to one-time charge for the vesting of performance-based awards upon receiving U.S. FDA approval of taletrectinib, $41.0 million increase in sales and marketing expenses, a $3.1 million increase in legal fees, a $0.1 million increase in professional fees and $0.2 million increase in other expenses offset by $1.5 million decrease in foreign currency impact.

Other Income (Expense), Net

The following table presents a breakdown of our other income (expense):

	Years Ended December 31,		
	2025	2024	Change
(In thousands)			
Other income (expense):			
Interest income	$ 21,430	$ 27,062	$ (5,632)
Interest expense	(13,682)	(341)	(13,341)
Investment advisory fees	(722)	(976)	254
Change in fair value of warrant liability	(812)	(936)	124
Realized gain (loss) on marketable securities	5	(12)	17
Net loss on fixed asset disposal	(33)	—	(33)
Other income (expense)	2,251	(109)	2,360
Total other income, net	$ 8,437	$ 24,688	$ (16,251)

Other income (expense), net decreased by $16.3 million for the year ended December 31, 2025 compared to 2024 primarily related to a decrease in interest income from investments of $5.6 million primarily due to lower treasury yield, a $13.3 million increase in interest expense offset by a $0.1 million decrease in the change in fair value of warrant liability, $2.3 million increase in other income due to government subsidy income and a $0.2 million decrease in investment advisory fees.

Liquidity, Capital Resources and Plan of Operations

From inception through December 31, 2024, our operations have been financed primarily by the sale and issuance of Series A preferred stock and common stock, including through the Merger and the PIPE investment. As of December 31, 2025, we had $529.2 million in cash, cash equivalents and marketable securities and an accumulated deficit of $1,115.4 million.

Our primary use of cash is to fund operating expenses, which consist of research and development expenses related to our clinical-stage product candidates and preclinical programs, and to a lesser extent, general and administrative expenses. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

On March 3, 2025, we announced the closing of a non-dilutive financing of up to $250.0 million from Sagard. The financing is comprised of a $150.0 million (the "Investment Amount") synthetic royalty financing agreement with Sagard Healthcare Partners (Delaware) II LP (the “RIF Agreement”) and a $100.0 million senior secured term loan with Sagard Holdings Manager LP (the “Loan Agreement”). The Investment Amount and a $50.0 million tranche of the term loan was funded on June 25, 2025, following FDA’s approval of IBTROZI. The second tranche of $50.0 million of the term loan will be available at our option until June 30, 2026, because we have achieved first U.S. commercial sale of IBTROZI.

Under the RIF Agreement, in exchange for the Investment Amount, we have agreed to make tiered royalty payments to Sagard on U.S. net sales of IBTROZI equal to 5.5% of annual U.S. net sales up to $600 million and 3.0% of annual U.S. net sales between $600 million and $1 billion. We will retain all annual U.S. net sales above $1 billion. Our obligation to make the royalty payments will cease upon the earliest occurrence of total royalty payments reaching 1.6 times of the Investment Amount by the calendar quarter ending on June 30, 2031, 1.75 times of the Investment Amount by the calendar quarter ending on June 30, 2034, or 2.0 times of the Investment Amount thereafter. To the extent we have not made royalty payments totaling at least 100% of the Investment Amount by February 1, 2043, we will be required to make a true up payment in an amount equal to such shortfall (the “True Up Payment”). In addition, if certain events occur, including certain bankruptcy events, non-payment of Payments, a change of control, expiration or termination of certain intellectual property rights or marketing authorization, an out-license or sale of all of the rights in and to IBTROZI in the United States and (subject to applicable cure periods) non-compliance with the covenants in the RIF Agreement, we may be required to repurchase the synthetical royalty financing at a repurchase price ranging from 1.4 to 2.0 times of the Investment Amount, depending on the time of such event, less all royalty payments we made by then under the Loan Agreement, the term loan will bear interest at the secured overnight

financing rate ("SOFR") plus a margin of 6.00%, subject to a 4.00% SOFR floor. There are no scheduled amortization payments associated with the term loan, with all outstanding principal due at maturity. The transaction will support the U.S. commercial launch of IBTROZI and general corporate purposes.

Based upon our current operating plan, we believe that our existing cash, cash equivalents and marketable securities as of December 31, 2025, will enable us to fund our operating expenses and capital expenditure requirements through at least the next 12 months.

We expect to incur substantial expenses in the foreseeable future for the development and commercialization of our product candidates and ongoing internal research and development programs. At this time, we cannot reasonably estimate the nature, timing or aggregate amount of costs for our development, commercialization, and internal research and development programs. However, in order to complete our current and future preclinical studies and clinical trials, and to complete the process of obtaining regulatory approval for our product candidates, as well as to commercialize our product candidates, we may require substantial additional funding in the future.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Years Ended December 31,	
	2025	2024
	(In thousands)	
Cash used in operating activities	$ (173,427)	$ (130,413)
Cash provided by investing activities	99,520	122,703
Cash provided by financing activities	202,535	331
Effect of foreign exchange rate changes on cash and cash equivalents	(265)	453
Net increase (decrease) in cash and cash equivalents	$ 128,363	$ (6,926)

Operating Activities

In 2025, cash used in operating activities of $173.4 million was attributable to a net loss of $204.6 million, net change of $12.0 million in our net operating assets and liabilities offset by non-cash charges of $43.2 million. The change in operating assets and liabilities was primarily due to a $3.4 million increase in accounts receivable, $11.4 million increase in inventory, $7.9 million decrease in contract liabilities, $4.3 million increase in prepaid expenses and other current assets, $0.8 million increase in other non-current assets offset by $3.1 million increase in accounts payable, $12.4 million increase in accrued expenses, and $0.3 million decrease in interest receivable on marketable securities. The non-cash charges consisted primarily of stock-based compensation of $35.9 million, $1.8 million of depreciation and amortization, $0.3 million of lease expense, $10.1 million in interest expense, $0.7 million of amortization of debt issuance costs, changes in fair value of warrant liability of $0.8 million offset by amortization of premium on marketable securities of $5.3 million, and $1.1 million of foreign currency transaction loss.

In 2024, cash used in operating activities of $130.4 million was attributable to a net loss of $567.9 million, a net change of $12.5 million in our net operating assets and liabilities offset by non-cash charges of $450.0 million. The change in operating assets and liabilities was primarily due to a $12.7 million increase in accounts receivable, $6.0 million increase in other non-current assets, $3.0 million increase in prepaid expenses and other current assets and $1.6 million decrease in accounts payable offset by a $6.8 million increase in accrued expenses, $3.9 million increase in contract liabilities and $0.1 million decrease in interest receivable on marketable securities. The non-cash charges consisted primarily of $425.1 million of acquired in-process research and development, stock-based compensation of $32.3 million, changes in fair value of warrant liability of $0.9 million, $0.7 million of depreciation and amortization and $0.2 million of net loss on disposal of property and equipment offset by amortization of premium on marketable securities of $9.0 million and $0.2 million of non cash lease expense.

Investing Activities

In 2025, cash provided by investing activities of $99.5 million was related to the $462.3 million of proceeds from the sale of marketable securities offset by purchase of marketable securities of $354.4 million, $8.0 million payment for capitalized market approval intangibles and $0.4 million purchase of property and equipment.

In 2024, cash provided by investing activities of $122.7 million was related to the $450.1 million of proceeds from the sale of marketable securities, $19.9 million cash acquired from the acquisition of AnHeart offset by purchase of marketable securities of $339.7 million, $7.4 million of transaction costs related to the acquisition of AnHeart and purchase of property and equipment of $0.2 million.

Financing Activities

In 2025, cash provided by financing activities of $202.5 million was related to the $150.0 million proceeds from the RIF Agreement, $60.1 million proceeds from borrowings, $10.1 million proceeds from exercise of options and $1.3 million of proceeds from issuance of Common Stock under the Employee Stock Purchase Plan offset by $6.6 million payment of debt issuance costs, $11.9 million of debt repayments, and $0.5 million payment for revenue interest financing agreement.

In 2024, cash provided by financing activities of $0.3 million was related to the $4.5 million proceeds from exercise of options and $0.4 million of proceeds from issuance of Common Stock under the Employee Stock Purchase Plan and $12.6 million of proceeds from borrowings offset by $17.2 million of debt repayments.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an on-going basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable in the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions. While our significant accounting policies are described in the notes to our consolidated financial statements, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

While our significant accounting policies are described in the notes to our consolidated financial statements, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

Revenue Recognition

We apply ASC Topic 606, "Revenue from Contracts with Customers" ("ASC 606") to account for our revenue transactions. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the five-step model. We only apply the five-step model to contracts when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer. Once a contract is determined to be within the scope of ASC 606 at contract inception, we review the contract to determine which performance obligations it must deliver and which of these performance obligations are distinct. We recognize as revenue the amount of the transaction price that is allocated to each performance obligation when that performance obligation is satisfied or as it is satisfied. The Company recognizes shipping and handling costs as an expense in cost of revenue. Accounts receivable represent amounts invoiced and revenues recognized prior to invoicing when we have satisfied our performance obligation and have the unconditional right to payment.

Product revenue, net

We recognize product revenue, net of variable consideration related to certain allowances and accruals, when the customer takes control of the product, which is typically upon delivery to the customer. Product revenue is recorded at the net sales price, or transaction price. We record product revenue reserves, which are classified as a reduction in product revenues, to account for the components of variable consideration. Variable consideration includes the following components: chargebacks, government rebates, commercial payor rebates, trade discounts and allowances, product returns, and co-payment assistance. Calculating certain of these items involves estimates and judgments based on sales or invoice data, contractual terms, historical utilization rates, new information regarding changes in applicable regulations and guidelines that would impact the amount of the actual rebates, our expectations regarding future

utilization rates and channel inventory data. We review the adequacy of our provisions for sales deductions on a quarterly basis. Amounts accrued for sales deductions are adjusted when trends or significant events indicate that adjustment is appropriate and to reflect actual experience. The most significant items deducted from gross product sales where we exercise judgment are rebates, sales returns and chargebacks.

Collaborative Arrangements

In November 2018, the FASB issued Topic 808, "Collaborative Arrangements" ("ASC 808"): Clarifying the Interaction between ASC 808 and ASC 606. This update clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer and precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue from contracts with customers if the counterparty is not a customer for that transaction. We adopted this standard for all periods presented. We enter into collaborative arrangements for the research and development, manufacture and/or commercialization of drug products and drug candidates. We assessed and determined that none of the collaboration agreements entered into during the periods presented were within the scope of ASC 808, as all of the agreements did not involve active participation by both parties in a joint research activity, and therefore did not qualify as collaborative arrangements under ASC 808. We have determined that all the elements of the above collaborations are reflective of a vendor-customer relationship and therefore within the scope of ASC 606. In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its agreements, we perform the five-step model under ASC 606 noted above. We recognize revenue to depict the transfer of control of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to receive in exchange for those goods or services. Our collaborative arrangements may contain more than one unit of account, or performance obligation, including grants of licenses to intellectual property rights, agreements to provide research and development services and other deliverables. The collaborative arrangements do not include a right of return for any deliverable. As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. In developing the stand-alone selling price for a performance obligation, we consider competitor pricing for a similar or identical product, market awareness of and perception of the product, expected product life and current market trends. In general, the consideration allocated to each performance obligation is recognized when the respective obligation is satisfied either by delivering a good or providing a service, limited to the consideration that is not constrained. Non-refundable payments received before all of the relevant criteria for revenue recognition are satisfied are recorded as contract liabilities.

Licenses of intellectual property

If a license to our intellectual property is determined to be distinct from the other promises or performance obligations identified in the contract, we recognize revenue from the portion of the transaction price allocated to the license at a point in time, when the license is transferred to the customer and the customer is able to benefit from the license.

Research and development services

The portion of a transaction price allocated to research and development services performance obligations is deferred and recognized as revenue over time as delivery or performance of such services occurs based on the use of an input method.

Customer options

A customer's right to choose, at its discretion, to make a payment for additional goods or services is generally considered an option. If we are not presently obligated to provide and does not have a right to consideration for delivering additional goods or services, the item is considered an option. We evaluate the customer options for material rights, such as the ability to acquire additional goods or services for free or a discount. Optional future services that reflect their standalone selling prices do not provide the customer with a material right and, therefore, are not considered performance obligations and are accounted for as separate contracts. The optional future services do not include a material right to be accounted for as performance obligations.

Milestone payments

Our collaboration agreements include development and regulatory milestones. We evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. We evaluate factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At the end of each reporting period, we re-evaluate the probability of achievement of such milestones and any related constraint, and if necessary, adjusts the estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and net loss in the period of adjustment. In December 2025, we received from NK $25.0 million upon achievement of a regulatory milestone. We recognized $21.2 million in license revenue and $3.8 million in research and development service revenue.

Royalties

For sales-based royalties, including milestone payments based on the level of sales, we determine whether the sole or predominant item to which the royalties relate is a license. When the license is the sole or predominant item to which the sales-based royalty relates, we recognize revenue at the later of: (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). For the years ended December 31, 2025 and 2024, we have recognized $1.3 million and nil, respectively, sales-based royalty revenue resulting from our collaboration agreements.

We receive payments from our customers based on billing terms established in the contract. Up-front payments and fees are recorded as contract liabilities (e.g., deferred revenue) upon receipt or when due until we perform our obligations under the arrangement.

In the event of an early termination of a collaboration agreement, any contract liabilities would be recognized in the period in which all our obligations under the agreement have been fulfilled. For a complete discussion of accounting for revenue, see the section titled "Collaboration and License Agreements" in Note 5 to our consolidated financial statements appearing elsewhere in this report.

Interest-bearing loans and borrowings

The carrying amount of the liability for sale of future royalties is based on management's estimate of the future royalties to be paid over the life of the arrangement using an imputed rate of interest. The liability is amortized using the effective interest rate method, resulting in recognition of non-cash interest expense over the estimated term of the agreement. If there are changes to the estimate, we recognize the impact to the liability’s amortization schedule and the related non-cash interest expense prospectively. Such costs are recognized under Interest expense in the Consolidated Statements of Operations and Comprehensive Loss and under Accrued expenses on the Consolidated Balance Sheets.

Acquisition of assets and businesses

Our consolidated financial statements include the operations of acquired businesses after the completion of the acquisitions. We account for acquired businesses using the acquisition method of accounting, which requires, among other things, that most assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date and that the fair value of acquired in-process research and development be recorded on the balance sheet. Transaction costs are expensed as incurred. Any excess of the consideration transferred over the assigned values of the net assets acquired is recorded as goodwill. When we acquire net assets that do not constitute a business, as defined in accounting principles generally accepted in the United States of America (“GAAP”), no goodwill is recognized and acquired in-process research and development is expensed in acquired in-process research and development expenses. Contingent consideration in a business combination is included as part of the acquisition cost and is recognized at fair value as of the acquisition date. Fair value is generally estimated by using a probability-weighted discounted cash flow approach. Any liability resulting from contingent consideration is remeasured to fair value at each reporting date until the contingency is resolved.

On April 9, 2024, we completed our acquisition of AnHeart. We accounted for the transaction as an asset acquisition since the lead asset represented substantially all of the fair value of the gross assets acquired.

Recent Accounting Pronouncements

For information about recent accounting pronouncements, see the sections titled "Significant Accounting Policies—Recent Accounting Pronouncements" in Note 2 to our consolidated financial statements for the year ended December 31, 2025 appearing elsewhere in this report.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

We had cash and investments of $529.2 million as of December 31, 2025, consisting of cash, money market funds, municipal bonds, certificate of deposits, exchange traded fund, government securities, commercial paper, and corporate bonds. To date, fluctuations in interest income have not been significant.

We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. We have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates.

Foreign Currency Risk

Our expenses are generally denominated in U.S. dollars. A 10% increase or decrease in current exchange rates would not have a material effect on our financial results.

Item 8. Financial Statements and Supplementary Data

This information appears following Item 15 of this report and is included herein by reference.

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

None

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, as defined in Rules 13a–15(e) and 15d–15(e) of the Exchange Act, as of December 31, 2025. Based on the evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2025.

We do not expect that our disclosure controls and procedures will prevent all errors and all instances of fraud. Disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Further, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and the benefits must be considered relative to their costs. Because of the inherent limitations in all disclosure controls and procedures, no evaluation of disclosure controls and procedures can provide absolute assurance that we have detected all our control deficiencies and instances of fraud, if any. The design of disclosure controls and procedures also is based partly on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Management's Report on Internal Controls Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with generally accepted accounting principles. 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.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2025, as required by Rule 13a-15(c) under the Exchange Act. In making this assessment, we used the criteria set forth in the framework in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on our evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2025.

Changes in Internal Control Over Financial Reporting

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

Item 9B. Other Information

Insider Trading Arrangements and Policies

During the Company's last fiscal quarter, the Company's directors and officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated the contracts, instructions or written plans for the purchase or sale of the Company's securities set forth below.

On December 4, 2025, David Hanley, the Company's Chief Technical Operations Officer, entered into a trading plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act, providing for the sale of up to 800,000 shares of the Company's Common Stock. Pursuant to this plan, Mr. Hanley may sell shares beginning April 4, 2026 and ending April 10, 2027.

On December 4, 2025, Gary Hattersley, the Company's Chief Scientific Officer, entered into a trading plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act, providing for the sale of up to 400,000 shares of the Company's Common Stock. Pursuant to this plan, Mr. Hattersley may sell shares beginning April 4, 2026 and ending April 1, 2027.

On December 4, 2025, David Liu, the Company's Chief Medical Officer, entered into a trading plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act, providing for the sale of up to 450,000 shares of the Company's Common Stock. Pursuant to this plan, Mr. Liu may sell shares beginning April 4, 2026 and ending April 10, 2027.

On December 4, 2025, Moses Makunje, the Company's Chief Accounting Officer, entered into a trading plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act, providing for the sale of up to 100,000 shares of the Company's Common Stock. Pursuant to this plan, Mr. Makunje may sell shares beginning April 4, 2026 and ending April 6, 2027.

On December 4, 2025, Stacy Markel, the Company's Chief People Officer, entered into a trading plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act, providing for the sale of up to 500,000 shares of the Company's Common Stock. Pursuant to this plan, Ms. Markel may sell shares beginning April 4, 2026 and ending April 6, 2027.

On December 4, 2025, Philippe Sauvage, the Company's Chief Financial Officer, entered into a trading plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act, providing for the

sale of up to 590,918 shares of the Company's Common Stock. Pursuant to this plan, Mr. Sauvage may sell shares beginning April 4, 2026 and ending April 15, 2027.

On December 4, 2025, Kerry Wentworth, the Company's Chief Regulatory Officer, entered into a trading plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act, providing for the sale of up to 475,090 shares of the Company's Common Stock. Pursuant to this plan, Ms. Wentworth may sell shares beginning April 4, 2026 and ending April 1, 2027.

Item 9C. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections

Not applicable

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K and is incorporated herein by reference to our definitive Proxy Statement for our next Annual Meeting of Stockholders (the "Proxy Statement"), which we intend to file pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, within 120 days after December 31, 2025.

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item concerning our directors and corporate governance is incorporated by reference to the information set forth in the section titled "Directors and Corporate Governance" in our Proxy Statement. Information required by this Item concerning our executive officers is incorporated by reference to the information set forth in the section entitled "Executive Officers of the Company" in our Proxy Statement. Information required by this Item regarding our Section 16 reporting compliance and code of business conduct and ethics is incorporated by reference to the information set forth in the section entitled "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" in our Proxy Statement.

Our written code of business conduct and ethics (the "Code of Conduct") applies to all of our employees, officers and directors, including our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. The Code of Conduct is available on our corporate website at investors.nuvationbio.com in the Investors section under "Governance Documents." If we make any substantive amendments to our Code of Conduct or grant any of our directors or executive officers any waiver, including any implicit waiver, from a provision of our Code of Conduct, we will disclose the nature of the amendment or waiver on our website or in a Current Report on Form 8-K.

In conformance with updated SEC regulations, we have adopted amended insider trading policies and procedures governing the purchase, sale and/or other dispositions of our securities by directors, officers and employees, or the Company itself, that are reasonably designed to promote compliance with insider trading laws, rules and regulations, and New York Stock Exchange standards. A copy of our insider trading policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K.

Item 11. Executive Compensation.

The information required by this Item regarding executive compensation is incorporated by reference to the information set forth in the sections titled "Executive Compensation" and "Compensation for Directors" in our Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item regarding security ownership of certain beneficial owners and management is incorporated by reference to the information set forth in the section titled "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" in our Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item regarding executive compensation is incorporated by reference to the information set forth in the sections titled "Certain Relationships and Related-Person Transactions," "Directors and Corporate Governance," and "Board of Directors and Committees" in our Proxy Statement.

Item 14. Principal Accountant Fees and Services.

The information required by this Item regarding principal accountant fees and services is incorporated by reference to the information set forth in the section titled "Principal Accountant Fees and Services" in our Proxy Statement.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report on Form 10-K:

1. Consolidated Financial Statements:

2. Consolidated Financial Statement Schedules

None.

3. Exhibits

We hereby file or incorporate by reference as part of this Annual Report on Form 10-K the exhibits listed in the attached Exhibit Index.

Exhibit Number	Description	Incorporated by Reference			
		Schedule/ Form	File No.	Exhibit	Filing Date
2.1+	Agreement and Plan of Merger, dated October 20, 2020	S-4/A	333-250036	2.1	January 8, 2021
3.1	Amended and Restated Certificate of Incorporation	8-K	001-39351	3.1	February 12, 2021
3.2	Amended and Restated Bylaws	8-K	001-39351	3.2	February 12, 2021
4.1	Specimen Class A Common Stock Certificate	S-4/A	333-250036	4.4	January 8, 2021
4.2	Specimen Warrant Certificate	S-1/A	333-239138	4.4	June 23, 2020
4.3	Warrant Agreement, dated June 30, 2020, between Continental Stock Transfer & Trust Company and the Registrant	S-1/A	333-239138	4.4	June 23, 2020
4.4	Description of Securities	10-K	001-39351	4.4	March 11, 2021
10.1	Form of PIPE Subscription Agreements	8-K	001-39351	10.1	October 21, 2020
10.2	Forward Purchase Agreement, dated June 30, 2020, between Registrant, EcoR1 Panacea Holdings, LLC, EcoR1 Capital Fund, L.P., EcoR1 Capital Fund Qualified, L.P. and EcoR1 Venture Opportunity Fund, L.P.	8-K	000-39315	10.7	July 6, 2020
10.3#	2021 Equity Incentive Plan, as amended	10-Q	001-39351	10.1	May 7, 2025
10.4#	Forms of Option Grant Notice and Option Agreement under the 2021 Equity Incentive Plan	8-K	001-39351	10.4	February 12, 2021
10.5#	Forms of RSU Award Grant Notice and Agreement under the 2021 Equity Incentive Plan	8-K	001-39351	10.5	February 12, 2021
10.6#	2021 Employee Stock Purchase Plan	8-K	001-39351	10.6	February 12, 2021
10.7#	2019 Equity Incentive Plan, as amended, of Legacy Nuvation Bio	S-4	333-250036	10.13	November 12, 2020
10.8#	Forms of Option Grant Notice and Option Agreement under the 2019 Equity Incentive Plan, as amended, of Legacy Nuvation Bio	S-4	333-250036	10.14	November 12, 2020
10.9#	Form of Indemnification Agreement	S-4/A	333-250036	10.8	January 19, 2021
10.10#	Severance and Change in Control Plan	S-4/A	333-250036	10.12	January 8, 2021
10.11	Amended and Restated Registration Rights Agreement, dated February 10, 2021, by and among the Registrant, the EcoR1 Panacea Holdings, LLC, Cowen Investments and certain other stockholders of the Registrant party thereto	8-K	001-39351	10.12	February 12, 2021
10.12	Letter Agreement, dated June 30, 2020, by and among the Registrant, EcoR1 Panacea Holdings, LLC, Cowen Investments, and the Registrant's officers and directors	8-K	001-39351	10.1	July 6, 2020
10.17‡	License and Commercialization Agreement between Nippon Kayaku Co., Ltd. and AnHeart Therapeutics Inc, dated October 27, 2023	8-K/A	001-39351	10.3	June 20, 2024

10.18‡	Collaboration and License Agreement between Innovent Biologics (Suzhou) Co. Ltd. and AnHeart Therapeutics Inc, dated May 31, 2021	8-K/A	001-39351	10.1	June 20, 2024
10.19‡	Amendment to Collaboration and License Agreement between Innovent Biologics (Suzhou) Co. Ltd. and AnHeart Therapeutics Inc, dated November 30, 2022	8-K/A	001-39351	10.2	June 20, 2024
10.20‡	License Agreement between Daiichi Sankyo Company, Limited and AnHeart Therapeutics Inc., dated December 7, 2018	10-Q	001-39351	10.3	May 14, 2024
10.21‡	First Amendment to License Agreement between Daiichi Sankyo Company, Limited and AnHeart Therapeutics Inc., dated August 17, 2020	10-Q	001-39351	10.4	May 14, 2024
10.22‡	License Agreement between Daiichi Sankyo Company, Limited and AnHeart Therapeutics Inc., dated September 7, 2020	10-Q	001-39351	10.5	May 14, 2024
10.23‡	Credit Agreement and Guaranty, dated March 3, 2025, among Registrant, Sagard Holdings Manager LP and other parties thereto	10-K	001-39351	10.23	March 6, 2025
10.24‡	Revenue Interest Financing Agreement, dated March 3, 2025, between Registrant and Sagard Healthcare Partners (Delaware) II LP	10-K	001-39351	10.24	March 6, 2025
10.25	Contract Manufacturing Agreement (API) between Registrant and Asymchem Laboratories (Tianjin) Co., Ltd., dated March 3, 2025	10-Q	001-39351	10.3	May 7, 2025
10.26	Contract Manufacturing Agreement (Drug Product) between Registrant and Asymchem Life Science (Tianjin) Co., Ltd., dated March 21, 2025	10-Q	001-39351	10.4	May 7, 2025
10.27*	Contract Manufacturing Agreement (API) between Registrant and Asymchem Laboratories (Tianjin) Co., Ltd., Amendment 1 dated July 9, 2025				
10.28*	Contract Manufacturing Agreement (API) between Registrant and Asymchem Laboratories (Tianjin) Co., Ltd., Amendment 2 dated December 9, 2025				
10.29*	Contract Manufacturing Agreement (Drug Product) between Registrant and Asymchem Life Science (Tianjin) Co., Ltd., Amendment 1 dated December 9, 2025				
10.30#	Non-Employee Director Compensation Policy	10-Q	001-39351	10.1	August 7, 2025
14.1*	Code of Business Conduct and Ethics				
16.1	Letter from Withum	8-K	001-39351	16.1	February 12, 2021
19.1*	Insider Trading Policy				
21.1*	List of Subsidiaries				

23.1*	Consent of KPMG LLP, independent registered public accounting firm				
24.1*	Power of Attorney (included on signature page).				
31.1*	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
31.2*	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
32.1**	Certification of Chief Executive Officer and Chief 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	Incentive Compensation Recoupment Policy	10-K	001-39351	97.1	February 29, 2024
97.2#	Employee Incentive Plan, dated January 21, 2025	10-K	001-39351	97.2	March 6, 2025
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents				
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)				

\+ Certain of the exhibits and schedules to this Exhibit have been omitted in accordance with Regulation S-K Item 601. The Registrant agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request.

\# Indicates a management contract or compensatory plan, contract or arrangement.

† Portions of this exhibit, as marked by asterisks, have been omitted in accordance with Regulation S-K Item 601.

* Filed herewith.

** Filed herewith and not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report, irrespective of any general incorporation language contained in such filing.

‡ Confidential portions of this Exhibit were redacted pursuant to Item 601(b)(10) of Regulation S-K and the Company agrees to furnish supplementally to the Securities and Exchange Commission a copy of any omitted schedule and/or exhibit upon request.

Item 16. Form 10K Summary

None.

SIGNATURES

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

NUVATION BIO INC.

Date: March 2, 2026

By: /s/ David Hung, M.D.

David Hung, M.D.
President and Chief Executive Officer

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints David Hung, M.D. and Philippe Sauvage, 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.

Signature	Title	Date
/S/ DAVID HUNG, M.D. **David Hung, M.D.**	Chairman of the Board, President and Chief Executive Officer (*Principal Executive Officer*)	March 2, 2026
/S/ PHILIPPE SAUVAGE **Philippe Sauvage**	Chief Financial Officer (*Principal Financial Officer*)	March 2, 2026
/S/ MOSES MAKUNJE **Moses Makunje**	VP, Finance *(Principal Accounting Officer)*	March 2, 2026
/S/ MIN CUI **Min Cui**	Director	March 2, 2026
/S/ ROBERT B. BAZEMORE, JR. **Robert B. Bazemore, Jr.**	Lead Independent Director	March 2, 2026
/S/ KIM BLICKENSTAFF **Kim Blickenstaff**	Director	March 2, 2026
/S/ KATHRYN E. FALBERG **Kathryn E. Falberg**	Director	March 2, 2026
/S/ ROBERT MASHAL, M.D. **Robert Mashal, M.D.**	Director	March 2, 2026
/S/ W. ANTHONY VERNON **W. Anthony Vernon**	Director	March 2, 2026

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors
Nuvation Bio Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Nuvation Bio Inc. and subsidiaries (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated 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 consolidated 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 consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a 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.

Accounting for the Sagard revenue interest financing arrangement

As described in Note 5 to the consolidated financial statements, the Company entered into a Revenue Interest Financing Agreement (the Financing Agreement) with Sagard Healthcare Partners (Delaware) II LP (the Investor), pursuant to which the Investor paid the Company $150 million (the Investment Amount) on June 25, 2025, following the FDA's approval of IBTROZI. In exchange for the Investment Amount, the Company has agreed to make tiered royalty payments to the Investor on U.S. net sales of IBTROZI. The Company accounted for the transaction as debt at the time the funding occurred and at amortized cost using the effective interest method. The Company will use the prospective method to account for changes in the effective interest rate arising from changes in the estimates of the revenue stream from the royalties. At the funding date, the Company recorded a $150.0 million liability.

We identified the accounting for the Financing Agreement as a critical audit matter. Subjective auditor judgment was required to evaluate judgments applied by management in determining the appropriate accounting treatment due to

the complexity involved in interpreting and applying the guidance for the accounting treatment as debt and evaluation of the contract terms and conditions, including embedded features, within the Financing Agreement.

The following are the primary procedures we performed to address this critical audit matter. We evaluated the design of certain internal controls related to management's accounting analysis process, including a control related to management's assessment of the terms and conditions of the Sagard arrangement. We inspected the Financing Agreement to identify and understand the terms and conditions that were relevant to the accounting for the transaction. We inspected the Company's accounting analysis for the transaction and evaluated whether the Company's analysis considered all relevant terms and conditions, including embedded features. We evaluated whether the Company's conclusion of the transaction's treatment as debt and conclusions over embedded features are in accordance with the relevant accounting guidance.

/s/ KPMG LLP

We have served as the Company's auditor since 2019.

New York, New York
March 2, 2026

NUVATION BIO INC. and Subsidiaries
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 164,086	$ 35,723
Accounts receivable, net of allowance for credit loss of $nil and $nil	16,076	12,722
Inventory	11,411	—
Prepaid expenses and other current assets	11,536	7,271
Marketable securities	365,125	466,969
Interest receivable on marketable securities	3,285	3,570
Total current assets	571,519	526,255
Property and equipment, net of accumulated depreciation of $1,184 and $874, respectively	564	586
Intangible assets, net of accumulated amortization of $1,856 and $448, respectively	11,214	4,622
Operating lease right-of-use assets	3,918	2,402
Other non-current assets	7,607	6,761
Total assets	$ 594,822	$ 540,626
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 9,479	$ 6,348
Current operating lease liabilities	1,880	1,663
Contract liabilities, current portion	7,515	11,117
Liability related to revenue interest financing agreement, current portion	9,585	—
Short-term borrowings	5,724	6,283
Warrant liability	2,865	—
Accrued expenses	45,183	32,833
Total current liabilities	82,231	58,244
Warrant liability	—	2,053
Contract liabilities, net of current portion	11,305	15,572
Non-current operating lease liabilities	2,543	969
Non-current liability related to revenue interest financing agreement, net of deferred financing costs of $4,241 and $0, respectively	145,819	—
Long-term borrowings, net of deferred financing costs of $3,042 and $0, respectively	47,208	—
Total liabilities	289,106	76,838
Commitments and contingencies (Note 16)		
Stockholders' equity		
Class A and Class B common stock and additional paid in capital, $0.0001 par value per share; 1,060,000,000 (Class A 1,000,000,000, Class B 60,000,000) shares authorized as of December 31, 2025 and December 31, 2024, 346,503,675 (Class A 345,503,675, Class B 1,000,000) and 337,837,872 (Class A 336,837,872, Class B 1,000,000) shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively	1,421,273	1,373,958
Accumulated deficit	(1,115,370)	(910,743)
Accumulated other comprehensive income	(187)	573
Total stockholders' equity	305,716	463,788
Total liabilities and stockholders' equity	$ 594,822	$ 540,626

The accompanying notes are an integral part of the consolidated financial statements.

NUVATION BIO INC. and Subsidiaries
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except per share data)

	For the Years Ended December 31,	
	2025	**2024**
Revenues:		
Product revenue, net	$ 24,663	$ —
Collaboration and license agreements revenue	38,239	7,873
Total revenues	62,902	7,873
Costs and expenses:		
Cost of sales	856	—
Cost of collaboration and license agreements revenue	8,442	7,078
Research and development	115,106	99,119
Acquired in-process research and development	—	425,070
Selling, general and administrative	151,562	69,233
Total costs and expenses	275,966	600,500
Loss from operations	(213,064)	(592,627)
Other income (expense):		
Interest income	21,430	27,062
Interest expense	(13,682)	(341)
Investment advisory fees	(722)	(976)
Change in fair value of warrant liability	(812)	(936)
Realized gain (loss) on marketable securities	5	(12)
Net loss on disposal of fixed assets	(33)	—
Other income (expense)	2,251	(109)
Total other income, net	8,437	24,688
Loss before income taxes	(204,627)	(567,939)
Provision for income taxes	—	—
Net loss	$ (204,627)	$ (567,939)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.60)	$ (2.11)
Weighted average common shares outstanding, basic and diluted	341,541	268,772
Comprehensive loss:		
Net loss	$ (204,627)	$ (567,939)
Other comprehensive loss, net of taxes:		
Currency translation adjustment	(1,501)	537
Change in unrealized gain (loss) on available-for-sale securities	741	(145)
Comprehensive loss	$ (205,387)	$ (567,547)

The accompanying notes are an integral part of the consolidated financial statements.

NUVATION BIO INC. and Subsidiaries
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share data)

	Convertible Preferred Stock		Common Stock and Additional Paid-in Capital			Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Class A Shares	Amount	Class A Shares	Class B Shares	Amount	Deficit	Income (Loss)	Equity
Balance, December 31, 2023	—	$ —	218,046,219	1,000,000	$ 947,745	$ (342,804)	$ 181	$ 605,122
Issuance of common stock for AnHeart acquisition	—	—	27,646,255	—	89,297	—	—	89,297
Issuance of convertible preferred stock related to the AnHeart acquisition	851,202	274,938	—	—	—	—	—	—
Conversion of preferred stock to common stock related to the AnHeart acquisition	(851,202)	(274,938)	85,120,200	—	274,938	—	—	274,938
Issuance of replacement awards related to the AnHeart acquisition	—	—	—	—	24,818	—	—	24,818
Issuance of common stock for purchase under ESPP	—	—	238,982	—	427	—	—	427
Issuance of common stock for RSUs vested	—	—	618,340	—	—	—	—	—
Exercise of stock options	—	—	5,167,876	—	4,458	—	—	4,458
Stock-based compensation	—	—	—	—	32,275	—	—	32,275
Net loss	—	—	—	—	—	(567,939)	—	(567,939)
Currency translation adjustment	—	—	—	—	—	—	537	537
Other comprehensive loss	—	—	—	—	—	—	(145)	(145)
Balance, December 31, 2024	—	—	336,837,872	1,000,000	1,373,958	(910,743)	573	463,788
Exercise of stock options	—	—	6,655,268	—	10,111	—	—	10,111
Issuance of Common Stock for RSUs vested	—	—	1,316,104	—	—	—	—	—
Issuance of Common Stock for purchase under the ESPP	—	—	694,431	—	1,310	—	—	1,310
Stock-based compensation	—	—	—	—	35,894	—	—	35,894
Net loss	—	—	—	—	—	(204,627)	—	(204,627)
Currency translation adjustment	—	—	—	—	—	—	(1,501)	(1,501)
Other comprehensive income	—	—	—	—	—	—	741	741
Balance, December 31, 2025	—	$ —	345,503,675	1,000,000	$ 1,421,273	$ (1,115,370)	$ (187)	$ 305,716

The accompanying notes are an integral part of the consolidated financial statements.

NUVATION BIO INC. and Subsidiaries
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

For the Years Ended December 31,	2025	2024
Cash flows from operating activities:		
Net loss	$ (204,627)	$ (567,939)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	35,894	32,275
Depreciation and amortization	1,739	683
Non-cash lease expense	275	(172)
Non-cash interest on revenue interest financing agreement	10,138	—
Amortization of debt issuance costs	662	—
Change in fair value of warrant liability	812	936
Amortization of premium and discounts on marketable securities	(5,284)	(9,000)
Realized loss (gain) on marketable securities	(5)	12
Net loss on disposal of property and equipment	33	229
Unrealized foreign currency transaction loss	(1,085)	—
Acquired in-process research and development	—	425,070
Change in operating assets and liabilities		
Accounts receivable	(3,354)	(12,722)
Prepaid expenses and other current assets	(4,265)	(3,010)
Inventory	(11,411)	—
Interest receivable on marketable securities	285	132
Other non-current assets	(846)	(6,033)
Accounts payable	3,131	(1,654)
Contract liabilities	(7,869)	3,942
Accrued expenses	12,350	6,838
Net cash used in operating activities	(173,427)	(130,413)
Cash flow from investing activities:		
Cash acquired from AnHeart acquisition	—	19,862
Transaction costs related to AnHeart acquisition	—	(7,434)
Purchases of marketable securities	(354,416)	(339,645)
Proceeds from sale of marketable securities	462,290	450,082
Purchases of property and equipment	(354)	(162)
Cash paid for capitalized market approval intangibles	(8,000)	—
Net cash provided by investing activities	99,520	122,703
Cash flow from financing activities:		
Proceeds from borrowings, net of issuance costs	60,102	12,609
Proceeds from revenue interest financing agreement	150,000	—
Payments on borrowings	(11,899)	(17,163)
Payments on debt issuance costs	(6,596)	—
Payment on revenue interest financing agreement	(493)	—
Proceeds from issuance of Common Stock under ESPP	1,310	427
Proceeds from exercises of options	10,111	4,458
Net cash provided by financing activities	202,535	331
Effect of foreign exchange rate changes on cash and cash equivalents	(265)	453
Net decrease in cash and cash equivalents	128,363	(6,926)
Cash and cash equivalents, beginning of the period	35,723	42,649
Cash and cash equivalents, end of the period	$ 164,086	$ 35,723
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 2,882	$ 341
Cash paid for tax	$ 197	$ 373
Non-cash operating activities:		
Right-of-use asset recognized	$ 3,871	$ 620
Operating lease liability recognized	$ 3,871	$ 608
Non-cash investing activities:		
Issuance of common stock related to the AnHeart acquisition	$ —	$ 89,297
Issuance of convertible preferred stock related to the AnHeart acquisition	$ —	$ 274,938
Issuance of warrants related to the AnHeart acquisition	$ —	$ 764
Issuance of replacement awards related to the AnHeart acquisition	$ —	$ 24,818

The accompanying notes are an integral part of the consolidated financial statements.

NOTE 1. DESCRIPTION OF ORGANIZATION AND BUSINESS OPERATIONS

Nuvation Bio Inc. and subsidiaries ("Nuvation Bio"), a Delaware corporation, is a global oncology company focused on tackling some of the toughest challenges in cancer treatment with the goal of developing therapies that create a profound, positive impact on patients' lives. Nuvation Bio was incorporated on March 20, 2018 (inception date) and has offices in New York, San Francisco, Boston and Shanghai.

On February 10, 2021, (the "Closing Date"), Nuvation Bio Inc., a Delaware corporation ("Legacy Nuvation Bio"), Panacea Acquisition Corp. ("Panacea"), and Panacea Merger Subsidiary Corp, a Delaware corporation and a direct, wholly owned subsidiary of Panacea ("Merger Sub") consummated the transactions contemplated by an Agreement and Plan of Merger among them dated October 20, 2020 ("Merger Agreement").

Pursuant to the terms of the Merger Agreement, a business combination of Panacea and Legacy Nuvation Bio was effected through the merger of Merger Sub with and into Legacy Nuvation Bio, with Legacy Nuvation Bio surviving as a wholly owned subsidiary of Panacea (the "Merger") and, collectively with the other transactions described in the Merger Agreement. On the Closing Date, Legacy Nuvation Bio changed its name to Nuvation Bio Operating Company Inc. and Panacea changed its name to Nuvation Bio Inc. (the "Company" or "Nuvation Bio").

On April 9, 2024 (the "Acquisition Date"), the Company completed its acquisition of AnHeart Therapeutics Ltd., an exempted company incorporated under the laws of the Cayman Islands ("AnHeart"), pursuant to that certain Agreement and Plan of Merger (the "AnHeart Merger Agreement"), by and among the Company, AnHeart, Artemis Merger Sub I, Ltd., an exempted company incorporated under the laws of the Cayman Islands and a wholly owned subsidiary of the Company, and Artemis Merger Sub II, Ltd., an exempted company incorporated under the laws of the Cayman Islands and a wholly owned subsidiary of the Company. Subsequent to the Acquisition Date, reference to AnHeart is used to represent the consolidated entity of the Company.

NOTE 2. SIGNIFICANT ACCOUNTING POLICIES

a. Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented.

b. Principles of Consolidation

The consolidated financial statements include the balances of the Company and its subsidiaries. All intercompany transactions and balances are eliminated in consolidation.

c. Liquidity

As of December 31, 2025, the Company has an accumulated deficit of approximately $1,115.4 million and net cash used in operating activities was approximately $173.4 million for the year ended December 31, 2025. Management expects to continue to incur operating losses and negative cash flows from operations for the foreseeable future.

As of December 31, 2025, the Company had cash, cash equivalents, and marketable securities of $529.2 million. The Company believes that its existing cash, cash equivalents, and marketable securities will be sufficient to meet its cash commitments for at least the next 12 months after the date that these consolidated financial statements are issued. The Company's research and development activities can be costly, and the timing and outcomes are uncertain. The assumptions upon which the Company has based its estimates are routinely evaluated and may be subject to change. The actual amount of the Company's expenditures will vary depending upon a number of factors including but not limited to the progress of the Company's commercialization efforts for IBTROZI, research and development activities, potential regulatory approval of its product candidates, and the level of financial resources available.

d. Significant Risks and Uncertainties

The Company's operations are subject to a number of factors that can affect its operating results and financial condition. Such factors include, but are not limited to: the results of research and development, clinical testing and trial activities of the Company's products, the Company's ability to obtain and maintain regulatory approval to market its products, competition from products manufactured and sold or being developed by other companies, the price of, and demand for, Company's products, the Company's ability to negotiate favorable licensing or other manufacturing and marketing agreements for its products, and the Company's ability to raise capital.

Developing and commercializing a product requires significant time and capital and is subject to regulatory review and approval as well as competition from other biotechnology and pharmaceutical companies. The Company operates in an environment of rapid change and is dependent upon the continued services of its employees and vendors and obtaining and protecting intellectual property.

e. 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 and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenue and expenses during the year. Accordingly, actual results could differ from those estimates and those differences could be significant. Significant estimates and assumptions reflected in the accompanying consolidated financial statements include, but are not limited to, the fair value of in-process research and development acquired, warrant liabilities, leases, stock options granted, revenue recognition, interest expense and depreciation expense.

f. Functional Currency and Foreign Currency Translations

The Company's reporting currency is the U.S. dollar ("USD"). The functional currency of the Company's subsidiaries incorporated in People Republic of China ("PRC") is Renminbi ("RMB"). The functional currency of the Company and its subsidiaries incorporated outside the PRC is USD. Transactions denominated in currencies other than the functional currencies are re-measured into the functional currency of the entity at the exchange rates prevailing on the transaction dates. Foreign currency denominated financial assets and liabilities are re-measured at the balance sheet date exchange rate. The resulting exchange differences are included in the net loss of the statements of operations and comprehensive loss. Assets and liabilities of the Company with functional currency other than USD are translated into USD at fiscal year-end exchange rates. Equity amounts are translated at historical exchange rates. Income and expense items are translated at average exchange rates during the fiscal year. Translation adjustments arising from these are reported as foreign currency translation adjustments and are shown as a component of other comprehensive income (loss).

g. Cash and Cash Equivalents

Cash equivalents include short-term, highly liquid instruments, consisting of money market accounts, a money market mutual fund and short-term investments with maturities from the date of purchase of 90 days or less. The majority of cash and cash equivalents are maintained with major financial institutions in North America. Deposits with these financial institutions may exceed the amount of insurance provided on such deposits. These deposits may be redeemed upon demand which reduces counterparty performance risk.

h. Marketable Securities

Debt securities have been classified as available-for-sale which may be sold before maturity as they are not classified as trading securities or as held-to-maturity securities. Marketable debt securities classified as available-for-sale are carried at fair value with unrealized gains or losses reported in other comprehensive income (loss). Exchange traded funds are equity securities, which are reported as marketable securities with readily determinable fair values, are also carried at fair value with unrealized gains and losses included in other (expense) income, net. Realized gains and losses on both debt and equity securities are included in other (expense) income, net.

For securities in an unrealized loss position, management considers the extent and duration of the unrealized loss, and the financial condition and near-term prospects of the issuer. Management also assesses whether it intends to sell, or it is more likely than not that it will be required to sell, a security in an unrealized loss position before

recovery of its amortized cost basis. If management determines there is any other than temporary impairment, the entire difference between amortized cost and fair value is recognized as impairment through earnings.

The Company is exposed to credit losses primarily through its available-for-sale investments. The Company assesses whether its available-for sale investments are impaired at each reporting period. Unrealized losses or impairments resulting from the amortized cost basis of any available-for-sale debt security exceeding its fair value are evaluated for identification of credit losses and non-credit related losses. Any credit losses are charged to earnings against the allowance for credit losses of the debt security, limited to the difference between the fair value and the amortized cost basis of the debt security. Any difference between the fair value of the debt security and the amortized cost basis, less the allowance for expected credit losses, are reported in other comprehensive income (loss). Expected cash inflows due to improvements in credit are recognized through a reversal of the allowance for expected credit losses subject to the total allowance previously recognized. The Company's expected loss allowance methodology for the debt securities includes reviewing the extent of the unrealized loss, the size, term, geographical location, and industry of the issuer, the issuers' credit ratings and any changes in those ratings, as well as reviewing current and future economic market conditions and the issuers' current status and financial condition. As of December 31, 2025, the Company has not recognized an allowance for expected credit losses related to available-for-sale investments as the Company has not identified any unrealized losses for these investments attributable to credit factors.

Interest income includes amortization and accretion of purchase premium and discount. Premiums and discounts on debt securities are amortized on the effective-interest method. Gains and losses on sales are recorded on the settlement date and determined using the specific identification method.

i. Acquisition of assets and businesses

Our consolidated financial statements include the operations of acquired businesses after the completion of the acquisitions. We account for acquired businesses using the acquisition method of accounting, which requires, among other things, that most assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date and that the fair value of acquired in-process research and development be recorded on the balance sheet. Transaction costs are expensed as incurred. Any excess of the consideration transferred over the assigned values of the net assets acquired is recorded as goodwill. When we acquire net assets that do not constitute a business, as defined in GAAP, no goodwill is recognized and acquired in-process research and development is expensed in acquired in-process research and development expenses. Contingent consideration in a business combination is included as part of the acquisition cost and is recognized at fair value as of the acquisition date. Fair value is generally estimated by using a probability-weighted discounted cash flow approach. Any liability resulting from contingent consideration is remeasured to fair value at each reporting date until the contingency is resolved.

On April 9, 2024, the Company completed its acquisition of AnHeart. The Company accounted for the transaction as an asset acquisition since the lead asset represented substantially all of the fair value of the gross assets acquired.

j. Concentration of Risk

Concentration of credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash, cash equivalents and marketable securities. The Company maintains its cash and cash equivalent balances in the form of business checking accounts and money market accounts, the balances of which, at times, may exceed federally insured limits. Exposure to cash and cash equivalents credit risk is reduced by placing such deposits with major financial institutions and monitoring their credit ratings. Marketable securities consist primarily of government and corporate bonds, municipal securities and exchange traded funds with fixed interest rates. Exposure to credit risk of marketable securities is reduced by maintaining a diverse portfolio and monitoring their credit ratings.

Concentration of customers

Below customers represent more than 10% of the Company's gross revenue for the years ended December 31, 2025 and 2024.

	For the Years Ended December 31,	
	2025	2024
Customer A	12.5%	65.4%
Customer B	40.8%	34.6%
Customer C	12.8%	—
Customer D	13.1%	—

Below customers represent more than 10% of the Company's balances of accounts receivable as of December 31, 2025.

	December 31,	
	2025	2024
Customer A	1,310	12,610
Customer B	2,387	—
Customer C	4,604	—
Customer D	4,727	—

k. Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the related assets of generally five years for computers and seven years for furniture and equipment. The cost of leasehold improvements is amortized on the straight-line method over the lesser of the estimated asset life or remaining term of the lease. Maintenance costs are expensed as incurred, while major betterments are capitalized.

l. Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable and an impairment assessment may be performed on the recoverability of the carrying amounts. If an impairment occurs, the loss is measured by comparing the fair value of the asset to its carrying amount.

m. Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC 815, Derivatives and Hedging ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own ordinary shares, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded as a liability at their fair value on the date of issuance and each balance sheet date thereafter. Changes in the estimated fair value of the warrants are recognized as a non-cash gain or loss on the statements of operations.

Following the Merger, there were 5,787,472 warrants to purchase common stock outstanding, consisting of 4,791,639 Public Warrants, 162,500 Private Placement Warrants and 833,333 Forward Purchase Warrants (as defined

below). Each whole warrant entitles the registered holder to purchase one share of our Class A common stock at a price of $11.50 per share. Pursuant to the warrant agreement, a warrant holder may exercise its warrants only for a whole number of shares of our Class A common stock.

As part of the consideration for AnHeart, the Company issued warrants collectively exercisable for approximately 2,893,720 shares of the Company's Class A Common Stock at an exercise price of $11.50 per share (the "Consideration Warrants"). The fair value of the Consideration Warrants was determined to approximate the public warrant trading price as of closing of the Acquisition, yielding a fair value of approximately $0.26 per share. The Consideration Warrants were restricted with respect to the exercise and transfer thereof until receipt of such stockholder approval and otherwise have terms identical to those of the Company's outstanding Public Warrants. Accordingly, the Consideration Warrants were restricted with respect to the exercise and transfer thereof until receipt of such stockholder approval and otherwise have terms identical to those of the Company's outstanding Public Warrants. Accordingly, the Company classified the Consideration Warrants as liabilities, consistent with the classification of the Company's Public Warrants. The Consideration Warrants are no longer restricted with respect to the exercise and transfer based on the stockholder approval from the 2024 Annual Meeting of Stockholders on September 3, 2024.

The Company evaluated Public Warrants, Private Placement Warrants, Consideration Warrants, and Forward Purchase Warrants (the "Warrants") under ASC 815-40, Derivatives and Hedging—Contracts in Entity's Own Equity, and concluded that they do not meet the criteria to be classified in stockholders' equity. Specifically, the settlement value of the Warrants is dependent, in part, on the holder of the Warrants at the time of settlement. Because the holder of an instrument is not an input into the pricing of a fixed-for-fixed option on our Common Stock, the Warrants fail the indexation guidance in ASC 815-40, which would preclude classification in stockholders' equity. Additionally, the exercise of the Warrants may be settled in cash upon the occurrence of a tender offer or exchange that involves more than 50% of the outstanding shares of the Company's Common Stock. Because not all of the Company's stockholders need to participate in such tender offer or exchange to trigger the potential cash settlement and the Company does not control the occurrence of such an event, the Company concluded that the Warrants do not meet the conditions to be classified in equity. Since the Warrants meet the definition of a derivative under ASC 815, the Company recorded these Warrants as liabilities on the balance sheet at fair value upon the closing of the Merger, with subsequent changes in their respective fair values recognized in the consolidated statement of operations and comprehensive loss at each reporting date. The fair value of Consideration, Public, and Forward Purchase Warrants was determined using the closing price of the publicly traded warrants on the NYSE market. The difference between the Public and Private Placement Warrants is that the Private Placement Warrants lack the redemption provision. As of December 31, 2025, since the Public Warrants can no longer be redeemed prior to expiration and are therefore identical to the Private Placement Warrants, the Private Placement Warrants were transferred from a Level 3 to a Level 1 fair value (see Note 3). The Warrants expired on February 10, 2026.

n. Revenue Recognition

The Company applies ASC Topic 606, "Revenue from Contracts with Customers" ("ASC 606") to account for its revenue transactions. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the five-step model. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer. Once a contract is determined to be within the scope of ASC 606 at contract inception, the Company reviews the contract to determine which performance obligations it must deliver and which of these performance obligations are distinct. The Company recognizes as revenue the amount of the transaction price that is allocated to each performance obligation when that performance obligation is satisfied or as it is satisfied. The Company recognizes shipping and handling costs as an expense in cost of revenue. Accounts receivable represents amounts invoiced and revenues recognized prior to invoicing when the Company has satisfied its performance obligation and has the unconditional right to payment.

Product revenue, net

The Company recognizes product revenue, net of variable consideration related to certain allowances and accruals, when the customer takes control of the product, which is typically upon delivery to the customer. Product revenue is recorded at the net sales price, or transaction price. The Company records product revenue reserves, which

are classified as a reduction in product revenues, to account for the components of variable consideration. Variable consideration includes the following components: chargebacks, government rebates, commercial payor rebates, trade discounts and allowances, product returns, and co-payment assistance. Calculating certain of these items involves estimates and judgments based on sales or invoice data, contractual terms, historical utilization rates, new information regarding changes in applicable regulations and guidelines that would impact the amount of the actual rebates, our expectations regarding future utilization rates and channel inventory data. We review the adequacy of our provisions for sales deductions on a quarterly basis. Amounts accrued for sales deductions are adjusted when trends or significant events indicate that adjustment is appropriate and to reflect actual experience. The most significant items deducted from gross product sales where we exercise judgment are rebates, sales returns and chargeback.

o. Collaborative Arrangement

In November 2018, the FASB issued Topic 808, "Collaborative Arrangements" ("ASC 808"): Clarifying the Interaction between ASC 808 and ASC 606. This update clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer and precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue from contracts with customers if the counterparty is not a customer for that transaction. The Company adopted this standard for all periods presented. The Company enters into collaborative arrangements for the research and development, manufacture and/or commercialization of drug products and drug candidates. The Company assessed and determined that none of the collaboration agreements entered into during the periods presented were within the scope of ASC 808, as all of the agreements did not involve active participation by both parties in a joint research activity, and therefore did not qualify as collaborative arrangements under ASC 808. The Company has determined that all the elements of the above collaborations are reflective of a vendor-customer relationship and therefore within the scope of ASC 606. In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its agreements, the Company performs the five-step model under ASC 606 noted above. The Company recognizes revenue to depict the transfer of control of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to receive in exchange for those goods or services. The Company's collaborative arrangements may contain more than one unit of account, or performance obligation, including grants of licenses to intellectual property rights, agreements to provide research and development services and other deliverables. The collaborative arrangements do not include a right of return for any deliverable. As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. In developing the stand-alone selling price for a performance obligation, the Company considers competitor pricing for a similar or identical product, market awareness of and perception of the product, expected product life and current market trends. In general, the consideration allocated to each performance obligation is recognized when the respective obligation is satisfied either by delivering a good or providing a service, limited to the consideration that is not constrained. Non-refundable payments received before all of the relevant criteria for revenue recognition are satisfied are recorded as contract liabilities.

Licenses of intellectual property

If a license to the Company's intellectual property is determined to be distinct from the other promises or performance obligations identified in the contract, the Company recognizes revenue from the portion of the transaction price allocated to the license at a point in time, when the license is transferred to the customer and the customer is able to benefit from the license.

Research and development services

The portion of a transaction price allocated to research and development services performance obligations is deferred and recognized as revenue over time as delivery or performance of such services occurs based on the use of an input method.

Customer options

A customer's right to choose, at its discretion, to make a payment for additional goods or services is generally considered an option. If the Company is not presently obligated to provide and does not have a right to consideration for delivering additional goods or services, the item is considered an option. The Company evaluates the customer options for material rights, such as the ability to acquire additional goods or services for free or a discount. Optional

future services that reflect their standalone selling prices do not provide the customer with a material right and, therefore, are not considered performance obligations and are accounted for as separate contracts. The optional future services do not include a material right to be accounted for as performance obligations.

Milestone payments

The Company's collaboration agreements include development and regulatory milestones. The Company evaluates whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and if necessary, adjusts the estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and net loss in the period of adjustment. In December 2025, we received from NK $25.0 million upon achievement of a regulatory milestone. The Company recognized $21.2 million in license revenue and $3.8 million in research and development service revenue.

Royalties

For sales-based royalties, including milestone payments based on the level of sales, the Company determines whether the sole or predominant item to which the royalties relate is a license. When the license is the sole or predominant item to which the sales-based royalty relates, the Company recognizes revenue at the later of: (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). For the years ended December 31, 2025 and 2024, the Company has recognized $1.3 million and nil, respectively, sales-based royalty revenue resulting from the Company's collaboration agreements.

The Company receives payments from its customers based on billing terms established in the contract. Up-front payments and fees are recorded as contract liabilities (e.g., deferred revenue) upon receipt or when due until the Company performs its obligations under the arrangement.

In the event of an early termination of a collaboration agreement, any contract liabilities would be recognized in the period in which all our obligations under the agreement have been fulfilled.

For a complete discussion of accounting for revenue, see Note 4, "Revenue Recognition."

p. Costs to Fulfill a Contract with a Customer

The Company has not capitalized any costs for the years ended December 31, 2025 and 2024. The Company is required to capitalize costs incurred to fulfill customer contracts. These costs are required to be amortized to expense on a systematic basis that is consistent with the transfer to the customer of the goods or services to which the asset relates, compared to previously being expensed as incurred. Elements of the costs primarily include (i) payroll and other related costs of personnel related directly to the contract activities; (ii) costs related to pre-clinical testing and clinical trials such as payments to contract research organizations ("CROs") and contract manufacturing organizations ("CMOs"), investigators, and clinical trial sites that conduct the contract activities; (iv) costs to develop the product candidates, including raw materials and supplies, product testing, depreciation, and facility-related expenses; and (v) other research and development costs.

q. Accounts Receivable

In general, accounts receivable consists of amounts due from customers, net of customer allowances for cash discounts, product returns and chargebacks. Our contracts with customers have standard payment terms. We analyze accounts that are past due for collectability, and regularly evaluate the creditworthiness of our customers so that we can properly assess and respond to changes in their credit profiles. As of December 31, 2025 and 2024, the credit profiles for the Company’s customers were deemed to be in good standing and an allowance for credit losses was not considered necessary.

r. Inventory

Inventories are stated at the lower of cost or net realizable value and recognized on a first-in, first-out ("FIFO") method. Inventory is capitalized based on when future economic benefit is expected to be realized.

The Company analyzes its inventory levels on a periodic basis to determine if any inventory is at risk for expiration prior to sale or has a cost basis that is greater than its estimated future net realizable value. Any adjustments are recognized through cost of goods sold in the period in which they are incurred.

The Company outsources the manufacturing of its products to contract manufacturers. The Company expects to use the inventory that is classified within current assets on its consolidated balance sheet over its operating cycle. Inventory that is not expected to be used over the Company's operating cycle is classified as a non-current asset.

s. Interest-bearing loans and borrowings

The carrying amount of the liability for sale of future royalties is based on management's estimate of the future royalties to be paid over the life of the arrangement using an imputed rate of interest. The liability is amortized using the effective interest rate method, resulting in recognition of non-cash interest expense over the estimated term of the agreement. If there are changes to the estimate, we recognize the impact to the liability's amortization schedule and the related non-cash interest expense prospectively. Such costs are recognized under Interest expense in the Consolidated Statements of Operations and Comprehensive Loss and under Accrued expenses on the Consolidated Balance Sheets.

t. Leases

The Company determines if an arrangement contains a lease at inception. For arrangements where the Company is the lessee, operating leases are included in operating lease right-of-use, or ROU assets; current operating lease liabilities; and non-current operating lease liabilities on its balance sheets. The Company currently does not have any finance leases.

Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at the commencement date. ROU assets also include any initial direct costs incurred and any lease payments made on or before the lease commencement date, less lease incentives received. The Company uses its incremental borrowing rate based on the information available at the commencement date in determining the lease liabilities as the Company's leases generally do not provide an implicit rate. The incremental borrowing rate is reevaluated upon a lease modification. The operating lease ROU asset also includes any initial direct costs and prepaid lease payments made less any lease incentives. The Company considered information available at the adoption date of Topic 842, "Leases" ("ASC 842") to determine the incremental borrowing rate for leases in existence as of this date. The incremental borrowing rate used was the weighted average rate between secured and unsecured lending arrangements. Lease terms may include options to extend or terminate the lease when the Company is reasonably certain that the option will be exercised. Variable payments included in the lease agreement are expensed as incurred. Lease expense is recognized on a straight-line basis over the lease term.

The Company elected to apply each of the practical expedients described in ASC Topic 842-10-65-1(f) which allow companies not to reassess: (i) whether any expired or existing agreements contain leases, (ii) the classification of any expired or existing leases, and (iii) the capitalization of initial direct costs for any existing leases. The Company also elected to apply the short-term lease measurement and recognition exemption in which ROU assets and lease liabilities are not recognized for short-term operating leases. A short-term operating lease is a lease that, at the commencement date, has a lease term of 12 months or less and does not include an option to purchase the underlying asset that the lessee is reasonably certain to exercise. The Company also elected not to separate non-lease components from lease components and instead to account for each separate lease component and the non-lease components associated with that lease component as a single lease component.

u. Segment Information

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company's operations are focused on oncology development activities. Substantially all revenues were derived from customers located in the U.S., China and Japan. For the year ended December 31, 2025, the revenues derived from customers located in the U.S., China and Japan were $24.7 million, $9.4 million and $28.8 million, respectively.

The Company's Chief Executive Officer is the Chief Operating Decision Maker ("CODM"). The CODM utilizes the Company's strategic product development roadmaps and financial models, as a key input to resource allocation. The CODM is regularly provided with actual, budgeted and forecasted expense information to make decisions on resource allocation and assess performance of the business and monitor budget versus actual results using income from operations.

Significant expenses within income from operations, as well as within net income, include cost of revenue, research and development, and selling, general and administrative expenses, which are each separately presented on the Company's Consolidated Statements of Operations and Comprehensive Loss. Other segment items within net income include interest income, interest expense, investment advisory fees, change in fair value of warrant liability, realized loss on marketable securities and other expense, net, and income tax expense.

v. Research and Development Costs

Costs incurred in connection with research and development activities are expensed as incurred. These costs include fees paid to consultants, vendors and various entities that perform certain research and testing on behalf of the Company.

The Company has acquired rights to develop and commercialize product candidates. Upfront payments that relate to the acquisition of a new product compound, as well as pre-commercial milestone payments, are immediately expensed as acquired in-process research and development in the period in which they are incurred, provided that the new product compound did not also include processes or activities that would constitute a "business" as defined under U.S. GAAP, and the product candidate has not achieved regulatory approval for marketing and, absent obtaining such approval, has no established alternative future use. Milestone payments made to third parties subsequent to regulatory approval which meet the capitalization criteria would be capitalized as intangible assets and amortized over the estimated remaining useful life of the related product. If the conditions enabling capitalization of development costs as an asset have not yet been met, all development expenditures are recognized in profit or loss when incurred.

w. Stock-based Compensation

The Company recognizes compensation cost for grants of employee stock options using a fair-value measurement method, that is recognized in operating results as compensation expense based on fair value over the requisite service period of the awards. Forfeitures are recorded as they occur instead of estimating forfeitures that are expected to occur.

The Company determines the fair value of stock-based awards that are based only on a service condition using the Black-Scholes option-pricing model which uses both historical and current market data to estimate fair value. The method incorporates various assumptions such as the risk-free interest rate, volatility, dividend yield, and expected life of the options.

The Company determines the fair value of stock-based awards that are based on both a service condition and achievement of the first to occur of a market or performance condition using a Monte Carlo simulation.

x. Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. The difference between the financial statement and tax basis of assets and liabilities is determined annually. Deferred income tax assets and liabilities are computed for those differences that have future tax consequences using the currently enacted tax laws and rates that apply to the years in which they are expected to affect taxable income. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense.

The Company uses a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken, or expected to be taken, in a tax return. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate. The Company's policy is to record interest and penalties related to income taxes as part of the tax provision. Returns for

tax years beginning with those filed for the period ended December 31, 2018 are open to federal and state tax examination.

y. Recent Accounting Pronouncements

In November 2024, the FASB issued Subtopic 220-40 "Disaggregation of Income Statement Expenses", which requires an entity to disclose, on an annual and interim basis, disaggregated information about certain income statement expense line items in a tabular format in the notes to the financial statements. The standard will be effective for annual reporting periods beginning after December 15, 2026 and for interim reporting periods within annual reporting periods beginning after December 15, 2027, with early adoption permitted, and may be applied either prospectively or retrospectively. We are currently evaluating the potential effect that the updated standard will have on our financial statement disclosures.

In December 2023, the FASB issued Topics 740 "Improvements to Income Tax Disclosures" to expand the disclosure requirements for income taxes, specifically related to the rate reconciliation and income taxes paid. This guidance is effective for our annual periods beginning January 1, 2025, with early adoption permitted. The Company adopted the new guidance prospectively effective January 1, 2025. The adoption of this guidance impacted disclosure only and did not have an effect on the Company's consolidated financial position, results of operations, or cash flows. Comparative prior-year information has not been retrospectively adjusted.

NOTE 3. FAIR VALUE MEASUREMENTS AND MARKETABLE SECURITIES

The Company provides disclosure of financial assets and financial liabilities that are carried at fair value based on the price that would be received upon sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value measurements may be classified based on the amount of subjectivity associated with the inputs to fair valuation of these assets and liabilities using the following three levels:

Level 1 — Inputs are unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2 — Inputs include quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (i.e., interest rates, yield curves, etc.) and inputs that are derived principally from or corroborated by observable market data by correlation or other means (market corroborated inputs).

Level 3 — Unobservable inputs that reflect the Company's estimates of the assumptions that market participants would use in pricing the asset or liability. The Company develops these inputs based on the best information available, including its own data.

The following table presents information about the Company's marketable securities and the Warrant liability as of December 31, 2025 and 2024, measured at fair value on a recurring basis, and indicates the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value. The Company's Warrant liabilities are included within the Level 1 and Level 3 fair value hierarchy. The fair value of the Consideration, Public and Forward Purchase Warrants is determined using the closing price of the warrants on the NYSE market. The fair value of the Private Placement Warrants is determined using the Black-Scholes option pricing formula. The primary unobservable input utilized in determining the fair value of the Private Warrants is the expected volatility. The expected volatility was estimated considering observable Public Warrant pricing, the Company's own historical volatility and the volatility of guideline public companies. The difference between the Public and Private Placement Warrants is that the Private Placement Warrants lack the redemption provision. As of December 31, 2025, since the Public Warrants can no longer be redeemed prior to expiration and are therefore identical to the Private Placement Warrants, the Private Placement Warrants were transferred from a Level 3 to a Level 1 fair value. The Warrants expired on February 10, 2026.

	December 31, 2025			
	Total	Level 1	Level 2	Level 3
	(In thousands)			
Financial assets:				
Cash equivalents:				
Money market funds	$ 52,339	$ 52,339	$ —	$ —
U.S. government and government agency securities	43,990	—	43,990	—
	96,329	52,339	43,990	—
Marketable securities:				
Certificate of deposits	3,918	—	3,918	—
Commercial paper	5,158	—	5,158	—
U.S. government and government agency securities	226,777	—	226,777	—
Corporate bonds	129,272	—	129,272	—
	365,125	—	365,125	—
Total financial assets:	$ 461,454	$ 52,339	$ 409,115	$ —
Financial liabilities:				
Warrants	$ 2,865	$ 2,865	$ —	$ —

	December 31, 2024			
	Total	Level 1	Level 2	Level 3
	(In thousands)			
Financial assets:				
Cash equivalents:				
Money market funds	$ 11,549	$ 11,549	$ —	$ —
	11,549	11,549	—	—
Marketable securities:				
Certificate of deposits	12,642	—	12,642	—
Commercial paper	18,227	—	18,227	—
U.S. government and government agency securities	355,170	—	355,170	—
Corporate bonds	80,930	—	80,930	—
	466,969	—	466,969	—
Total financial assets:	$ 478,518	$ 11,549	$ 466,969	$ —
Financial liabilities:				
Warrants	$ 2,053	$ 1,959	$ —	$ 94

Marketable securities consist primarily of U.S. government and government agency, certificate of deposits, commercial paper, corporate bond and municipal securities ("Debt Securities"). Based on the Company's intentions regarding its marketable securities, all Debt Securities are classified as available-for-sale and are carried at fair value based on the price that would be received upon sale of the security.

The following table provides the amortized cost, aggregate fair value, and unrealized gains (losses) of marketable securities as of December 31, 2025 and December 31, 2024:

	December 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
	(In thousands)			
Cash equivalents:				
Money market funds	$ 52,339	$ —	$ —	$ 52,339
U.S. government and government agency securities	43,985	5	—	43,990
	96,324	5	—	96,329
Marketable securities:				
Certificate of deposits	3,909	9	—	3,918
Commercial paper	5,154	4	—	5,158
U.S. government and government agency securities	226,247	530	—	226,777
Corporate bonds	129,044	249	(21)	129,272
	364,354	792	(21)	365,125
	$ 460,678	$ 797	$ (21)	$ 461,454

	December 31, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
	(In thousands)			
Cash equivalents:				
Money market funds	$ 11,549	$ —	$ —	$ 11,549
	11,549	—	—	11,549
Marketable securities:				
Certificate of deposits	12,628	14	—	12,642
Commercial paper	18,200	27	—	18,227
U.S government and government agency securities	355,214	436	(480)	355,170
Corporate bonds	80,891	119	(80)	80,930
	466,933	596	(560)	466,969
	$ 478,482	$ 596	$ (560)	$ 478,518

For the years ended December 31, 2025 and 2024, the activity related to the net gains (losses) on marketable securities included in other income (expense) on the consolidated statements of operations and comprehensive loss were as follows (in thousands):

	Years Ended December 31,	
	2025	2024
Net realized gains (losses) on available-for-sale securities were as follows:		
Realized gains from sales of available-for-sale securities	$ 6	$ 41
Realized losses from sales of available-for-sale securities	(1)	(53)
Net realized gains (losses) on marketable securities	$ 5	$ (12)

The following tables provide marketable securities with continuous unrealized losses for less than 12 months and 12 months or greater and the related fair values as of December 31, 2025 and 2024 were as follows:

	December 31, 2025					
	Less than 12 Months		12 Months or Greater		Total	Total
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
	(In thousands)					
Corporate bonds	$ 18,157	$ (21)	$ —	$ —	$ 18,157	$ (21)
	$ 18,157	$ (21)	$ —	$ —	$ 18,157	$ (21)

	December 31, 2024					
	Less than 12 Months		12 Months or Greater		Total	Total
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
	(In thousands)					
Commercial paper	243	—	—	—	243	—
U.S. government and government agency securities	111,021	(398)	45,099	(82)	156,120	(480)
Corporate bonds	20,659	(33)	9,911	(47)	30,570	(80)
	$ 131,923	$ (431)	$ 55,010	$ (129)	$ 186,933	$ (560)

Maturity information based on fair value of the available-for-sale securities is as follows as of December 31, 2025:

	Within one year	After one year through five years	Total
		(In thousands)	
Certificate of deposits	$ 3,918	$ —	$ 3,918
Commercial paper	5,158	—	5,158
U.S. government and government agency securities	171,790	54,987	226,777
Corporate bonds	41,885	87,387	129,272
	$ 222,751	$ 142,374	$ 365,125

Debt and Liability Related to Revenue Interest Financing Agreement

As of December 31, 2025, the estimated fair value of our debt approximated the carrying amount. The fair value of the debt was estimated for disclosure purposes only and was determined based on other inputs that are observable, and thus categorized as Level 2 in the fair value hierarchy. The fair value of the liability related to the sale of future royalties is based on our current estimates of future royalties expected to be paid to Sagard over the life of the arrangement. The Company periodically reassesses the amount and timing of estimated royalty payments based on internal sales projections and external information from market data sources, which are considered Level 3 inputs. As of December 31, 2025, the estimated fair value of the liability approximated the carrying amount.

NOTE 4. REVENUE RECOGNITION

The Company revenues by geographic region for the years ended December 31, 2025 and 2024 are summarized as follows (in thousands):

	For the Years Ended December 31,	
	2025	2024
United States	$ 24,663	$ —
China	9,410	5,147
Japan	28,829	2,726
Total revenues	$ 62,902	$ 7,873

Net Product Revenue

Net product revenue was approximately $24.7 million for the year ended December 31, 2025 from the U.S. sales of IBTROZI. We began shipping IBTROZI to our U.S. customers in June 2025.

Collaboration and License Agreements Revenue

The Company enters into collaborative arrangements for the research and development, and commercialization of drug products and drug candidates. To date, these collaborative arrangements have included out-licensing of and options to out-license in-licensed compounds to other parties. These arrangements may include non-refundable upfront payments, contingent obligations for potential development, regulatory and commercial performance milestone payments, cost reimbursement arrangements, product supply and royalty payments.

In-Licensing Arrangements with Daiichi Sankyo Company Ltd. ("DS")

The Company has in-licensed the rights to develop, manufacture and commercialize multiple development stage drug candidates globally or in specific territories. The development milestone payments are recognized when the achievement of the associated milestone becomes probable and estimable and have been expensed before regulatory approval has been obtained. In December 2024, a $2.0 million development milestone payment was capitalized as an intangible asset upon regulatory approval in China. We reached two milestones in 2024, and the resulting $6 million in development milestone payments owed were paid to DS in March 2025. In June 2025, upon regulatory approval in the U.S., an $8 million milestone payment was owed to DS under the arrangement. This milestone payment was paid in July 2025 and was capitalized as an intangible asset.

Out-Licensing Arrangements

The Company's revenue related to its out-licensing collaborative agreements consist of product revenue, upfront license fees, royalty revenue and research and development services revenue from its collaboration agreements with Innovent Biologics Co. Ltd. ("Innovent") and Nippon Kayaku Co., Ltd. ("NK") for taletrectinib (also known as "AB-106").

Collaboration and License Agreement with Innovent

In May 2021, AnHeart entered into an agreement with Innovent, granting Innovent a sub-licensable, royalty-bearing, exclusive right and license to commercialize AB-106 in the People's Republic of China and Taiwan (the "Innovent Territory"). AnHeart is responsible for funding ongoing clinical trials of AB-106, regulatory submissions after development with Innovent responsible for commercialization. Under the agreement, AnHeart received a non-refundable upfront cash payment, $12.0 million for achievement of certain regulatory approval milestones, and is eligible to receive up to $17.0 million upon achievement of additional regulatory milestones, up to $105.0 million upon achievement of commercial milestones, and tiered percentage royalties ranging from mid-teen to low-twenties on annual net sales of taletrectinib in the Innovent Territory subject to certain adjustments.

For the year ended December 31, 2025, the Company recognized research and development service revenue of $5.3 million, sales of products supply of $2.4 million, and royalties of $1.1 million.

For the year ended December 31, 2024, the Company recognized research and development service revenue of $3.1 million, and license revenue of $2.1 million. As of December 31, 2025 and 2024, the accounts receivable of Innovent was $1.3 million and $12.6 million, respectively.

Collaboration and License Agreement with NK

In October 2023, AnHeart entered into an agreement with NK, granting NK a sub-licensable, royalty-bearing, exclusive right and license to commercialize AB-106 in Japan (the "NK Territory"). AnHeart is responsible for funding ongoing clinical trials of AB-106 in the NK Territory, with NK responsible for funding regulatory submissions in the NK Territory. The Company also granted NK a sub-licensable, royalty-bearing, exclusive right and license to research, develop and commercialize any new indications of AB-106 in the NK Territory ("NK New Indication Right"). Under the agreement, AnHeart received a non-refundable upfront cash payment of $40.0 million and is eligible to receive $25.0 million upon achievement of a regulatory milestone ("Regulatory Milestone Payment"), up to $35.0 million upon achievement of commercial milestones, and a lower-mid double digit percentage royalty on net sales of taletrectinib in the NK Territory. In September 2025, taletrectinib was approved by Japan's Ministry of Health, Labour, and Welfare. Since the regulatory approval has now been obtained, all remaining contract liability for research and development service from the initial upfront payment was recognized as revenue. In December 2025, upon receipt of the Regulatory Milestone Payment, the Company recognized $21.2 million in license revenue and $3.8 million in research and development service revenue.

Contract assets and contract liabilities

When the Company satisfies its performance obligations by providing services to a customer before the customer pays consideration and before payment is due, the Company recognizes its rights to consideration as a contract asset.

The Company did not recognize any contract assets as of December 31, 2025.

When a customer pays consideration before the Company provides services, the Company records its obligation as a contract liability representing the transaction price allocated to the remaining performance obligations. The contract liabilities as of December 31, 2025 of $18.8 million are expected to be recognized as revenue as research and development services are provided over the next 3 years, with $7.5 million expected to be recognized within one year of the balance sheet date.

The Company recognized $8.3 million of revenue in 2025 that was included in the contract liability balance at December 31, 2024.

The costs incurred to fulfill customer contracts were capitalized and amortized to cost of revenue on a systematic basis that is consistent with the transfer of research and development services to the customer to which the asset relates. For the year ended December 31, 2025, $5.2 million of costs incurred to fulfill customer contracts were capitalized and expensed in the same period. There were no balances related to the costs incurred to fulfill customer contracts as of December 31, 2025.

NOTE 5. BORROWING

In 2020, AnHeart entered into loan agreements with Bank of Hangzhou to obtain short-term borrowings to supplement its working capital. As of December 31, 2025, the outstanding balance net of repayments was $5.7 million. For the year ended December 31, 2025, the Company had drawn down $11.2 million and repaid $11.2 million. The fixed interest rate of the outstanding borrowings is 3.50% per annum.

On April 4, 2023, AnHeart entered into a Loan and Security Agreement with Shanghai Pudong Development Bank in Silicon Valley for up to 40.0 million RMB or equivalent in optional currency USD term loans ("SSVB Loan"). The SSVB Loan consists of a short-term working capital loan of 20 million RMB, which matured on April 4, 2024, and a long-term loan of 20 million RMB, which matured on April 4, 2025, at which time all outstanding balances were due. Draws on the line of credit for the short-term loans are payable on the maturity date of the SSVB Loan. As of December 31, 2025, there was no outstanding line of credit balance. For the year ended December 31, 2025, the Company repaid $0.7 million.

Loan Agreement

On March 3, 2025 (the "Loan Closing Date"), the Company entered into a $100.0 million senior secured loan agreement (the "Loan Agreement"), with Sagard Holdings Manager LP ("Sagard") as administrative agent, and the lenders party thereto. The $50.0 million tranche of the term loan was funded on June 25, 2025, following the U.S. Food and Drug Administration's ("FDA") approval of IBTROZI. The second tranche of $50.0 million of the term loan will be available at our option until June 30, 2026, because we have achieved first U.S. commercial sale of IBTROZI.

The senior secured loans under the Loan Agreement (the "Loans") mature on September 30, 2030 and bear interest at a variable annual rate equal to the secured overnight financing rate (subject to a 4.00% floor) plus a margin of 6.00%, payable quarterly. The Company will be required to pay a funding fee equal to a low single-digit percentage of each tranche, upon, and subject to, funding of such tranche, and an exit fee equal to a nominal percentage of each tranche upon repayment of such tranche.

The Company may voluntarily prepay the Loans at any time subject to a prepayment premium which, until the second anniversary of the initial funding date, is equal to the amount of interest that would have been paid up to, but not including, the second anniversary of such date, plus 3.00% of the principal amount of the Loans being repaid. Thereafter, the prepayment premium equals 3.00% of the principal amount of the Loans being repaid and is reduced over time until the fourth anniversary date, after which no prepayment premium is required. The Company is required to make mandatory prepayments of the Loans with net cash proceeds from certain asset sales or insurance proceeds or condemnation awards, in each case, subject to certain exceptions and reinvestment rights.

The obligations of the Company under the Loan Agreement are guaranteed by certain of its existing subsidiaries and are required to be guaranteed by subsequently acquired or organized subsidiaries, subject to certain exceptions (collectively, the "Guarantors"). The obligations of the Company under the Loan Agreement and the related guarantees thereunder are secured, subject to customary permitted liens and other agreed upon exceptions, by (i) a pledge of all of the equity interests of the Company's and the Guarantors' direct subsidiaries, and (ii) a perfected security interest in substantially all of the Company's and the Guarantors' tangible and intangible assets.

The Loan Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness, and dividends and other distributions, subject to certain exceptions. In addition, the Loan Agreement contains a financial covenant requiring that the Company maintain not less than $25 million of cash and certain cash equivalent investments. Failure of the Company to comply with the financial covenant will result in an event of default, subject to certain cure rights of the Company other than under certain specified circumstances.

The Loan Agreement contains events of default which are customary for financings of this type, in certain circumstances subject to customary cure periods. Following an event of default and any cure period, if applicable, Sagard will have the right upon notice to terminate any undrawn commitments and may accelerate all amounts outstanding under the Loan Agreement, in addition to other remedies available to it as a secured creditor of the Company.

The following table presents future minimum payments, including interest and the end of term charge, under the Loan Agreement as of December 31, 2025:

	December 31, 2025
	(In thousands)
2026	$ 5,069
2027	5,069
2028	5,083
2029	5,070
2030	54,042
Total	74,333
Less: imputed interest	(24,083)
Less: unamortized debt discount and issuance costs	(3,042)
Total loan agreement	$ 47,208

Revenue Interest Financing Agreement

On the Loan Closing Date, the Company also entered into a Revenue Interest Financing Agreement (the "Financing Agreement") with Sagard Healthcare Partners (Delaware) II LP (the "Investor"), pursuant to which the Investor paid the Company $150 million (the "Investment Amount") on June 25, 2025, following the FDA's approval of IBTROZI. In exchange for the Investment Amount, the Company has agreed to make tiered royalty payments to the Investor (the "Payments") on U.S. net sales of IBTROZI equal to 5.5% of annual U.S. net sales up to $600 million and 3.0% of annual U.S. net sales between $600 million and $1 billion. The Company will retain all annual U.S. net sales above $1 billion. The obligation to make the Payments will cease upon the earliest occurrence of total Payments reaching 1.6 times of the Investment Amount by the calendar quarter ending on June 30, 2031, 1.75 times of the Investment Amount by the calendar quarter ending on June 30, 2034, or 2.0 times of the Investment Amount thereafter.

The Company is required to make a true up payment to the Investor to the extent the Investor has not received Payments equaling at least 100% of the Investment Amount by February 1, 2043 in an amount equal to any such shortfall.

The Company's obligations under the Financing Agreement are secured, subject to customary permitted liens and other agreed upon exceptions and subject to an intercreditor agreement with Sagard, by a perfected security interest in (i) accounts receivable arising from U.S. net sales of IBTROZI and (ii) intellectual property, product registrations and regulatory approvals related to commercialization of IBTROZI in the United States.

The Company has the right, but not the obligation (the "Call Option"), to buy out the Investor's interest in the Payments at a repurchase price (the "Put/Call Price") equal to (a) on or prior to the second anniversary of the Loan Closing Date, an amount equal to 140% of the Investment Amount, less all Payments made to the applicable repurchase date, (b) after the second anniversary but on or prior to August 1, 2031, an amount equal to 160% of the Investment Amount, less all Payments made to the applicable repurchase date, (c) after August 1, 2031 but on or prior to August 1, 2034, an amount equal to 175% of the Investment Amount, less all Payments made to the applicable repurchase date, and (d) after August 1, 2034, an amount equal to 200% of the Investment Amount, less all Payments made to the applicable repurchase date.

The Financing Agreement contains customary representations and warranties and certain restrictions on the Company's ability to incur indebtedness and grant liens on intellectual property, product registrations and regulatory approvals related to commercialization and development of taletrectinib in the United States. In addition, the Financing Agreement provides that if certain events ("Put Option Events") occur, including certain bankruptcy events, non-payment of Payments, a change of control, expiration or termination of certain intellectual property rights or marketing authorization, an out-license or sale of all of the rights in and to taletrectinib in the United States and (subject to applicable cure periods) non-compliance with the covenants in the Financing Agreement, the Investor may require the Company to repurchase its interests in the Payments at the Put/Call Price.

The Financing Agreement was recorded as debt at the time the funding occurred and is accounted for at amortized cost using the effective interest method. The Company uses the prospective method to account for changes in the effective interest rate arising from changes in the estimates of the revenue stream from the royalties.

The following table shows the activity within the liability related to the Finance Agreement for the year ended December 31, 2025:

	Liabilities Related to Finance Agreement (in thousands)
Carrying value of liability related to Finance Agreement at June 25, 2025	$ 150,000
Issuance costs	(4,662)
Payments on Finance Agreement	(493)
Non-cash interest expense	10,138
Amortization of issuance costs	421
Carrying value of liability related to Finance Agreement at December 31, 2025	$ 155,404

NOTE 6. PROPERTY AND EQUIPMENT

Property and equipment, net consisted of the following:

	December 31,	
	2025	2024
	(In thousands)	
Computers	$ 771	$ 629
Furniture and fixtures	413	478
Leasehold improvements	536	353
Construction in process	28	—
Total property and equipment	1,748	1,460
Less accumulated depreciation and amortization	(1,184)	(874)
Total property and equipment, net	$ 564	$ 586

Depreciation and amortization expense related to property and equipment was $0.3 million and $0.7 million for the years ended December 31, 2025 and 2024, respectively.

NOTE 7. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	December 31,	
	2025	2024
	(In thousands)	
Accrued consultant fees	$ 17,232	$ 16,243
Accrued employee compensation	20,001	14,818
Accrued rebates and other sales-related accruals	5,061	—
Accrued royalty expense	1,478	—
Accrued professional fees	805	827
Accrued other taxes	286	679
Accrued other	320	266
	$ 45,183	$ 32,833

NOTE 8. LEASES

Our principal executive offices are located in New York, New York, where we lease approximately 7,900 square feet of office space under a lease that terminates in 2027, with an option for us to extend the lease for an additional five years which is not reasonably assured of exercise, and in San Francisco, where we lease approximately 19,418 square feet of office space that terminates in 2029. We also occupy office space located in Burlington, Massachusetts,

where we lease approximately 2,235 square feet of office space under a lease that terminates in 2027, as well as a total of approximately 1,799 square meters of office space in the People's Republic of China, in the cities of Beijing, Guangzhou, Hangzhou and Shanghai, under leases that terminate in 2026 through 2029.

Operating lease expense was $2.8 million and $2.5 million for the years ended December 31, 2025 and 2024, respectively. Expense related to variable leases was not significant for the years ended December 31, 2025 and 2024. Operating cash flows for the year ended December 31, 2025 and 2024 included $2.5 million and $2.6 million, respectively.

The following table presents the future minimum lease analysis of the Company's operating lease liabilities showing the aggregate lease payments as of December 31, 2025.

	December 31, 2025
	(In thousands)
2026	$ 2,192
2027	1,407
2028	1,219
2029	162
Total undiscounted lease payments	4,980
Less: imputed interest	(557)
Total operating lease liabilities	$ 4,423

The weighted average incremental borrowing rate used to determine the operating lease liabilities was 9.02%. The Company's weighted average remaining lease term was 2.64 years as of December 31, 2025.

As of December 31, 2025, the Company had $21.6 million of total undiscounted future payments under operating leases that have not yet commenced, which were not included on the consolidated balance sheet. The operating lease will commence in the second half of 2026.

NOTE 9. STOCKHOLDERS' EQUITY

Common Stock

As of December 31, 2025, the Founder owns 100% of the outstanding Class B common stock.

Common Stock Restriction Agreement

As a result of the Merger, the shares subject to the "Stock Restriction Agreement" between the Company and the Founder was adjusted based on the Exchange Ratio. The number of shares, as adjusted, subject to repurchase per the terms of the Stock Restriction Agreement is reduced each month by 1,101,240 Class A common shares and no common shares will be subject to repurchase by June 2022. As of December 31, 2025, there are no shares of Class A Common Stock subject to the repurchase option.

Voting

Holders of Class A and Class B common stock are entitled to one vote per share on all matters, except that the holders of Class A common stock do not participate in the election of the directors who are elected exclusively by the holders of Class B common stock. Holders of Class A and Class B common stock vote together as a single class on all matters, except that (i) the holders of Class B common stock have the right, voting as a separate class, to elect and remove without cause three directors plus at least 50% of any directors in excess of seven, and (ii) the approval of the holders of a majority of Class B common stock, voting as a separate class, is required for approval by the stockholders of any acquisition (whether by merger, sale of shares or sale of assets) or liquidation. There are no cumulative voting rights.

Conversion

Each share of Class B common stock will automatically convert into one share of Class A common stock upon transfer to a non-authorized holder. In addition, the Class B common stock is subject to a "sunset" provision under which all outstanding shares of Class B common stock will automatically convert into an equal number of shares of Class A common stock if ownership of shares of Class A and Class B common stock held by our President and Chief executive Officer, David Hung, M.D., falls below an aggregate of 43,188,000 shares or if Dr. Hung dies, becomes disabled or ceases to be our Chief Executive Officer, unless he is terminated from such position by us without cause.

NOTE 10. NET LOSS PER SHARE

Basic loss per share is computed by dividing net loss by the weighted-average number of shares of Class A and Class B common stock outstanding, but excluding shares of common stock subject to repurchase for the period. The number of common stock shares subject to repurchase was determined prospectively from the date of the Stock Restriction Agreement described in Note 9. Diluted loss per share reflects the potential dilution that could occur if the stock options to issue common stock were exercised. The Company had a net loss in all periods presented thus the dilutive net loss per common share is the same as the basic net loss per common share as the effect of any options or conversions is anti-dilutive.

The earnings per share amounts are the same for the different classes of common stock because the holders of each class are legally entitled to equal per share distributions whether through dividends or liquidation.

The following securities outstanding at December 31, 2025 and 2024 have been excluded from the calculation of weighted average shares outstanding:

	As of December 31,	
	2025	**2024**
Warrants	8,681,182	8,681,182
Class A common stock options	73,963,104	57,729,709
Restricted stock units	104,027	1,420,131

NOTE 11. ACCUMULATED OTHER COMPREHENSIVE (LOSS) INCOME

The following table presents a rollforward of the changes in accumulated other comprehensive (loss) income for the years ended December 31, 2025 and 2024, which is all attributable to unrealized gains (losses) on available-for-sale securities and currency translation adjustment. All amounts are net of tax.

	2025	2024
	(In thousands)	
Balance at beginning of period	$ 573	$ 181
Unrealized gain (loss)	746	(157)
Amount reclassified for realized (gain) loss on marketable securities	(5)	12
Currency translation adjustment	(1,501)	537
Balance at end of period	$ (187)	$ 573

NOTE 12. STOCK-BASED COMPENSATION

The 2021 Equity Incentive Plan

In March 2019, the Company adopted the 2019 Equity Incentive Plan or ("2019 Plan"), which provided for the grant of options, stock appreciation rights, restricted stock, and other stock awards. In January 2021, our board of directors adopted the 2021 Equity Incentive Plan (the "2021 Plan"). The 2021 Plan was approved by our stockholders in February 2021 and became effective immediately upon the Closing Date of the Merger. Shares available for future issuance under the 2019 Plan were canceled.

Awards. The 2021 Plan provides for the grant of incentive stock options ("ISOs"), within the meaning of Section 422 of the Code to employees, including employees of any parent or subsidiary, and for the grant of nonstatutory stock options ("NSOs"), stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards

and other forms of awards to employees, directors and consultants, including employees and consultants of our affiliates.

Authorized Shares. The maximum number of shares of Class A common stock that may be issued under the 2021 Plan was initially set at 50,684,047 shares of Class A common stock. The number of shares of Class A common stock reserved for issuance under the 2021 Plan will automatically increase on January 1 of each year, starting on January 1, 2022 through January 1, 2031, in an amount equal to (1) 4.0% of the total number of shares of Class A common stock and Class B common stock outstanding or issuable upon conversion or exercise of outstanding instruments on December 31 of the preceding year, or (2) a lesser number of shares of Class A common stock determined by our board of directors prior to the date of the increase. The maximum number of shares of Class A common stock that may be issued on the exercise of ISOs under the 2021 Plan is three times the number of shares available for issuance upon the 2021 Plan becoming effective or 152,052,141 shares.

The Employee Stock Purchase Plan

In January 2021, our board of directors adopted the 2021 Employee Stock Purchase Plan (the "ESPP"). The ESPP was approved by our stockholders in February 2021 and became effective immediately upon the Closing Date of the Merger.

Share Reserve. The maximum number of shares of Class A common stock that may be issued under the 2021 ESPP was initially set at 4,750,354 shares of Class A common stock. The number of shares of Class A common stock reserved for issuance under the 2021 ESPP will automatically increase on January 1st of each year, beginning on January 1, 2022 and continuing through and including January 1, 2031, by 1.0% of the total number of shares of Class A common stock and Class B common stock outstanding or issuable upon conversion or exercise of outstanding instruments on December 31st of the preceding calendar year or such lesser number of shares of Class A common stock as determined by our board of directors. Shares subject to purchase rights granted under the 2021 ESPP that terminate without having been exercised in full will not reduce the number of shares available for issuance under the 2021 ESPP.

The stock-based compensation expense included in the Company's Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2025 and 2024 is as follows (in thousands):

	Years ended December 31,	
	2025	2024
Research and development	$ 15,560	$ 16,450
General and administrative	20,334	15,825
	$ 35,894	$ 32,275

Options with Service Conditions

Options granted with only service conditions generally vest over four years and expire after ten years. Stock option activity with service condition only for employees and members of the Company's Board of Directors for the year ended December 31, 2025 is as follows:

	Shares Issuable Pursuant to Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	53,808,557	$ 2.70		
Granted	24,889,115	$ 2.05		
Forfeited	(1,899,489)	$ 2.49		
Exercised	(6,614,381)	$ 1.51		
Outstanding at December 31, 2025	70,183,802	$ 2.59	7.71	$ 450,519
Exercisable at December 31, 2025	30,955,882	$ 3.08	6.41	$ 185,349

All unvested options as of December 31, 2025 are expected to vest. The weighted average grant-date fair value of stock options outstanding on December 31, 2025 and 2024 was $2.59 and $2.23 per share, respectively. Total unrecognized compensation costs related to non-vested stock options at December 31, 2025 was $51.3 million and is expected to be recognized within future operating results over a weighted-average period of 2.61 years.

For stock options granted with only service conditions during the years ended December 31, 2025 and 2024, the inputs in the Black-Scholes option-pricing model to determine the fair value is as follows:

	December 31,	
	2025	2024
Exercise price	$1.76 - $8.96	$0.08 - $3.83
Risk-free interest rate	3.69% - 4.42%	3.63% - 4.74%
Expected volatility	72% - 75%	72% - 75%
Expected term in years	5.50 - 6.08	2.00 - 6.08
Dividend	0%	0%

The Company estimated its expected stock volatility based on the blended average of its historical volatility and of a publicly traded set of peer companies. The expected term of the Company's options has been determined utilizing the "simplified" method. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Dividend yield is based on the expectation that the Company will not pay any cash dividends in the foreseeable future.

Options with Service, Market, and Performance Conditions

Options granted with combined service, market, and performance conditions will vest based on achievement of various service conditions and either a market-based or performance-based goals in three tranches with multiple categories such as the Company's market capitalization, and clinical and regulatory milestones. The market-based and performance-based goals period ends in October 2030. The explicit service periods are three years for tranche 1, four years for tranche 2, and five years for tranche 3. Upon the vesting requirement, 20% of the options will vest for each of tranche 1 and 2, and 60% of the options granted for tranche 3 will vest. The Company recognizes the fair value of the options within each tranche over the longer of their explicit service period or derived service period. The achievement of the performance condition was not deemed probable on the date of grant. As of December 31, 2025, the performance condition was not deemed probable. The expense recognized is based on the fair value of the market condition for the years ended December 31, 2025 and 2024. Stock option activity with combined service, market, and performance conditions for employees for the year ended December 31, 2025 is as follows:

	Shares Issuable Pursuant to Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	3,921,152	$ 6.18		
Granted	—	$ -		
Forfeited	(125,350)	$ 4.11		
Exercised	(16,500)	$ 4.66		
Outstanding at December 31, 2025	3,779,302	$ 6.25	5.71	$ 13,379
Exercisable at December 31, 2025	1,935,138	$ 6.36	5.02	$ 6,391

The weighted average grant-date fair value of stock options outstanding on December 31, 2025 and 2024 was $6.25 and $3.95 per share, respectively. Total unrecognized compensation costs related to non-vested stock options at December 31, 2025 was $1.1 million and is expected to be recognized within future operating results over a weighted-average period of 1.51 years.

For the year ended December 31, 2025, there were no stock options granted with combined service, market, and performance conditions.

Restricted Stock Units

The following table summarizes the activity for the restricted stock units assumed in the AnHeart acquisition for the year ended December 31, 2025.

	Restricted Stock Units
Non-vested at December 31, 2024	1,420,131
Granted	—
Vested	(1,316,104)
Forfeited or canceled	—
Non-vested at December 31, 2025	104,027

The weighted average grant-date fair value of stock options outstanding on December 31, 2025 was $3.23. Total unrecognized compensation costs related to non-vested stock options at December 31, 2025 was $0.4 million and is expected to be recognized within future operating results over a weighted-average period of 2.24 years.

NOTE 13. 401(K) PLAN

The Company sponsors a 401(k) plan (the "Plan") covering substantially all employees of the Company. The Plan allows employees to contribute tax deferred salary deductions into the Plan under the provisions of Section 401(k) of the Internal Revenue Code. Matching contributions are made by the Company up to a maximum amount of 3% of employee contributions, subject to certain limitations as defined in the Plan. The Company made matching contributions of $1.7 million and $0.8 million for the years ended December 31, 2025 and 2024, respectively.

NOTE 14. WARRANTS

Following the Merger, there were 5,787,472 warrants to purchase Common Stock outstanding, consisting of 4,791,639 Public Warrants, 162,500 Private Placement Warrants and 833,333 Forward Purchase Warrants. Each whole warrant entitles the registered holder to purchase one share of our Class A Common Stock at a price of $11.50 per share. Pursuant to the warrant agreement, a warrant holder may exercise its warrants only for a whole number of shares of our Class A Common Stock.

Following the Acquisition, the Company issued 2,893,720 Consideration Warrants. The Consideration Warrants were restricted with respect to the exercise and transfer thereof until receipt of such stockholder approval and otherwise have terms identical to those of the Company's outstanding Public Warrants. The Consideration Warrants are no longer restricted with respect to the exercise and transfer thereof based on the stockholder approval obtained at the 2024 Annual Meeting of Stockholders on September 3, 2024.

At December 31, 2025, there were an aggregate of 8,681,182 warrants outstanding.

The Company concluded that the Consideration Warrants, Public Warrants, Private Warrants and Forward Purchase Warrants do not meet the conditions to be classified in equity. The warrants were recorded at fair value with subsequent changes in fair value reflected in earnings (see Note 3). The change in fair value resulted in a loss of $0.8 million during the year ended December 31, 2025.

The fair value of Consideration, Public and Forward Purchase Warrants is determined using the closing price of the warrants on the NYSE market and the related Warrant liability is included in Level 1 fair value measurements. The Company utilizes the Black-Scholes option pricing formula to determine the fair value of the Private Warrants at each reporting period, with changes in fair value recognized in the statement of operations. The estimated fair value of the warrant liability for the Private Warrants is determined using Level 3 inputs. Inherent in a binomial options pricing model are assumptions related to expected share-price volatility, expected life, risk-free interest rate and dividend yield. The annualized volatility of the Warrant was based on a calibration to the publicly traded warrant price as of the valuation date. The risk-free interest rate was estimated using linear interpolation assuming a term consistent with the time until the warrants expire, and yield information was based on U.S. Treasury Constant Maturities. The

expected life of the warrants is assumed to be equivalent to their remaining contractual term. The dividend rate is based on the historical rate, which the Company anticipates remaining at zero.

The difference between the Public and Private Placement Warrants is that the Private Placement Warrants lack the redemption provision. As of December 31, 2025, since the Public Warrants can no longer be redeemed prior to expiration and are therefore identical to the Private Placement Warrants, the Private Placement Warrants were transferred from a Level 3 to a Level 1 fair value. The Warrants expired on February 10, 2026.

The aforementioned warrant liabilities are not subject to qualified hedge accounting.

The Company determined the following fair values for the outstanding Warrants (in thousands):

	December 31, 2025
Public Warrants	$ 1,581
Private Warrants	54
Forward Purchase Warrants	275
Consideration Warrants	955
Total	$ 2,865

The following presents changes in liabilities classified in Level 3 of the fair value hierarchy for the year ended December 31, 2025 (in thousands):

	Year Ended December 31, 2025
Beginning balance	$ 94
Change in fair value of Private Warrants liability recognized in earnings	(40)
Ending balance	$ 54

NOTE 15. INCOME TAXES

The Company adopted ASU 2023-09 effective January 1, 2025 using the prospective method. Accordingly, enhanced disclosures are provided for fiscal year 2025. Comparative prior-period disclosures for 2024 are presented consistent with prior guidance, except where disclosure expansion was practicable.

The Company did not record a provision or benefit for income taxes for the years ended December 31, 2025 and 2024.

Effective Tax Rate Reconciliation (Enhanced disclosure under ASU 2023-09)

For fiscal year 2025, the Company presents both percentage and dollar impacts of reconciling items, as required for public business entities under ASU 2023-09.

Reconciling Item	Year Ended December 31, 2025	
	Amount	% of Pretax Income
Federal statutory rate	$ (41,690)	20.39%
State income taxes, net of federal tax benefit	2	0.00%
Foreign taxes effect:		
China		
Change in valuation allowance	(9,328)	4.56%
Deferred only adjustment	17,483	(8.55)%
Other	(8,154)	3.99%
Effects of changes in tax laws or rates enacted in current period	—	0.00%
Effects of cross-border tax laws	—	0.00%
Tax credits	(3,731)	1.82%
Changes in valuation allowances	43,163	(21.11)%
Nontaxable or nondeductible items	2,390	(1.17)%
Changes in unrecognized tax benefits	—	0.00%
Other items	(135)	0.06%
Effective tax rate	$ —	0.00%

ASU 2023-09 requires separate disclosure of reconciling items that exceed 5% of the statutory rate. No individual reconciling item exceeded that threshold in 2025.

Reconciling Item	Year Ended December 31, 2024 (Presented under prior guidance)
Federal statutory rate	21.00%
State income taxes, net of federal tax benefit	5.06%
Acquired IPR&D	(19.65)%
Stock based compensation	(0.31)%
Tax credits	0.72%
True-up	0.04%
Acquisition	10.25%
Change in rate	6.49%
Other items	0.66%
Valuation allowance	(24.26)%
Effective tax rate	0.00%

Dollar amounts for reconciling items were not previously required and are not presented for 2024 due to prospective adoption.

Income Taxes Paid

Under ASU 2023-09, income taxes paid must be disaggregated by federal, state, and foreign jurisdictions and further disaggregated by individual jurisdiction when payments exceed 5% of total income taxes paid.

Income taxes paid for the years ended December 31, 2025 and 2024 were immaterial.

The components of the net deferred tax asset as of December 31, 2025 and 2024 are as follows:

	December 31,	
	2025	2024
	(In thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 127,345	$ 107,698
Research and development tax credits	23,376	19,379
Capitalized research and development costs*	78,792	97,294
Stock-based compensation	8,872	13,172
Accrued bonus	3,980	4,116
Lease liability	945	930
Other	1,655	—
Total deferred tax assets	244,965	242,589
Deferred tax liabilities:		
Right of use asset	(811)	(853)
Other	—	(3,591)
Total deferred tax liabilities	(811)	(4,444)
Valuation allowance	(244,154)	(238,145)
Net deferred tax assets	$ —	$ —

*Capitalized costs deferred tax asset includes research and development capitalized expenditures of $33.5 million under IRC 59(e) and $43.4 million under IRC 174.

As of December 31, 2025, the Company had federal net operating loss carryforwards of approximately $330.6 million and state net operating loss carryforwards of approximately $440.5 million. The federal net operating losses have an unlimited carryover period and state net operating losses begin to expire in 2038.

As of December 31, 2025, the Company had federal research and development tax credit carryforwards of approximately $18.6 million and state research and development tax credit carryforwards of approximately $3.4 million. The federal research and development tax credits begin to expire in 2039 and state research and development tax credits have an unlimited carryover period.

As of December 31, 2025, the Company had federal orphan drug tax credit carryforwards of approximately $11.3 million. The federal orphan drug tax credits begin to expire in 2042.

All of the federal and state net operating losses may be subject to change of ownership limitations provided by the Internal Revenue Code and similar state provisions. An annual loss limitation may result in the expiration or reduced utilization of the net operating losses.

Under Sections 382 and 383 of the Code, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50 percentage-point cumulative change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. As a result of AnHeart Therapeutics, Inc.’s previous mergers with AnHeart Hangzhou in March 2019 and AnHeart Ltd (Cayman) in September 2021, we are subject to the Section 382 limitation with respect to AnHeart’s tax attributes. Our utilization of these pre-merger NOL and tax credit carryforwards is limited to the amount of income that the related entity contributes to our consolidated taxable income.

As of December 31, 2025, the Company maintained a full valuation allowance on its net deferred tax assets. The valuation allowance was determined in accordance with the provisions of ASC 740, Accounting for Income Taxes, which requires an assessment of both positive and negative evidence when determining whether it is more likely than not that deferred tax assets are recoverable. Such assessment is required on a jurisdiction by jurisdiction basis. The Company’s history of cumulative losses, along with expected future U.S. losses required that a full valuation allowance be recorded against all net deferred tax assets. The Company intends to maintain a full valuation allowance on net deferred tax assets until sufficient positive evidence exists to support reversal of the valuation allowance.

As of December 31, 2025, the Company’s total amount of unrecognized tax benefits was $10.1 million, none of which would impact the Company’s effective tax rate, if recognized. The Company does not anticipate that the amount of unrecognized tax benefit will significantly increase within the next 12 months.

For the years ended December 31, 2025 and 2024, the activity related to the unrecognized tax benefits were as follows (in thousands):

	Years Ended December 31,	
	2025	2024
Unrecognized tax benefits at beginning of year	$ 7,391	$ 5,629
Gross increases - current year tax positions	1,561	1,788
Gross decreases - prior year tax positions	1,181	(26)
Unrecognized tax benefits at end of year	$ 10,133	$ 7,391

The Company is subject to taxation in the United States and various state jurisdictions. All tax years remain subject to examination for U.S. federal and state purposes. All net operating losses generated to date are subject to adjustment for U.S. federal and state purposes. The Company is not currently under examination in federal or state jurisdictions.

The One Big Beautiful Bill Act ("OBBBA") was passed by the U.S. Congress in 2025 and signed into law by President Trump on July 4, 2025. The OBBBA includes a broad range of tax reform provisions, such as the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act, modifications to the international tax framework and the restoration of favorable tax treatment for certain business provisions. The legislation has multiple effective dates, with certain provisions effective in 2025 and others implemented through 2027. The impacts of these provisions do not have a material impact on the consolidated financial statements.

NOTE 16. COMMITMENTS AND CONTINGENCIES

Commitments

The Company leases its office space under non-cancellable operating lease agreements. The leases also require the Company to pay real estate taxes and other operational expenses associated with the leased location and is included in rent expense. The effect of graduating rents, net of the rent credits, is being amortized over the life of the lease so as to result in equal monthly rent expense over the lease term. Deferred rent liability reported in the accompanying consolidated balance sheets represents the cumulative excess of straight-line rental costs over the actual rental payments.

The Company has standby letters of credit with banks in the aggregate amount of $1.8 million which serve as security for the New York and San Francisco spaces operating leases. The standby letters of credit automatically renew annually.

The Company has certain non-cancelable purchase obligations related to the manufacturing of drug substance and drug product, and a commercial supply agreement with Asymchem Laboratories and Patheon Pharmaceuticals Inc., under which the Company has agreed to purchase a significant portion of its requirements for the drug substance over the next 6 months. Under these agreements, as of December 31, 2025, the Company is obligated to pay up to an aggregate of $8.0 million.

Contingencies

From time to time, the Company may be involved in routine litigation that arises in the ordinary course of business. There are no pending significant legal proceedings to which the Company is a party, for which management believes the ultimate outcome would have a material adverse effect on the Company’s financial position.

NOTE 17. SUBSEQUENT EVENT

On January 11, 2026, Nuvation Bio Inc. (the “Company”) entered into a License and Collaboration Agreement (the “License Agreement”) with Eisai Co., Ltd. (“Eisai”). Pursuant to the License Agreement, the Company granted Eisai an exclusive license to develop and commercialize licensed products containing taletrectinib in the following territories: the European Union and all member states thereof, Albania, Andorra, Armenia, Azerbaijan, Belarus, Bosnia and Herzegovina, Georgia, Kosovo, Moldova, Monaco, Montenegro, North Macedonia, San Marino, Serbia, Switzerland, Ukraine, Vatican City, the United Kingdom, Russia, Turkey, Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, the United Arab Emirates, Israel, Jordan, Iran, Iraq, Libya, Lebanon, Egypt, Sudan, Morocco, Algeria, Tunisia,

Australia, New Zealand, Canada, Singapore, Philippines, Indonesia, Thailand, Malaysia, Vietnam and India (collectively, the "Territory"), for upfront consideration of €50 million. Furthermore, in connection with the development and commercialization of the licensed products in the Territory, Eisai will be obligated to pay the Company a near-term regulatory milestone of €25 million and up to an aggregate of €120 million upon the achievement of certain sales milestones. In addition, Eisai is required to pay to the Company certain tiered royalties at rates in the low- to high-teens on aggregate annual net sales of licensed products during the applicable royalty term, subject to certain customary reductions.

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