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

FORM 10-K

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

For the fiscal year ended December 31, 2025

☐ **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: **000-55136**

Skye Bioscience, Inc.

(Exact name of registrant as specified in its charter)

Nevada	**45-0692882**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
11250 El Camino Real, Suite 100, San Diego, CA	**92130**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(858) 410-0266**

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

Title of Class:	Trading Symbol(s)	Name of each exchange on which registered:
Common Stock, par value $0.001	**SKYE**	**Nasdaq Global Market**

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

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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. ☐ Yes ☒ No

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. ☐ Yes ☒ No

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). ☐ Yes ☒ No

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates was approximately $129,530,291 as of June 30, 2025, based upon the closing price of $4.18 per share of the registrant's common stock on the Nasdaq Global Market on June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter.

As of March 9, 2026, there were 33,378,764 shares of the registrant's common stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with the registrant's 2026 Annual Meeting of Stockholders, which will be filed subsequent to the date hereof, are incorporated by reference into Part III of this Form 10-K. Such proxy statement will be filed with the Securities and Exchange Commission not later than 120 days following the end of the registrant's fiscal year ended December 31, 2025.

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PART I

Forward-Looking Statements

This Annual Report on Form 10-K for the year ended December 31, 2025 (this "Annual Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and the Private Securities Litigation Reform Act of 1955. Written or oral statements that constitute forward-looking statements may be made by us or on our behalf. Words such as “expect,” “anticipate,” “intend,” “plan,” “believe,” “estimate,” “may,” “will,” “should,” “could,” “target,” “strategy,” “intend,” “project,” “guidance,” “likely,” “usually,” “potential,” or the negative of these words or variations of such words, similar expressions, or comparable terminology are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. There are a number of important risks and uncertainties that could cause our actual results to differ materially from those indicated by forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. These forward-looking statements are based on current, estimates, forecasts and projections about the industry and markets in which we operate, and management’s beliefs, assumptions and expectations. These statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict and may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by any forward-looking statements.

These risks, uncertainties and other factors include, but are not limited to, risks associated with the following:

- the results of our research and development activities, including uncertainties relating to the discovery of potential product candidates and the preclinical and clinical testing of such potential product candidates;
- the timing, progress and results of our clinical studies for nimacimab (such as the extension arm of our Phase 2a CBeyond™ clinical trial);
- the early stage of nimacimab, which is presently under development;
- our ability to obtain and, if obtained, maintain regulatory approval of nimacimab, and any of our other future product candidates, and any related restrictions, limitations, and/or warnings in the label of any approved product candidate;
- our ability to retain or hire key scientific or management personnel;
- our ability to protect our intellectual property rights that are valuable to our business, including patent and other intellectual property rights;
- our dependence on third party manufacturers, suppliers, research organizations, testing laboratories and other potential collaborators, including global supply chain disruptions;
- our ability to develop successful sales and marketing capabilities in the future as needed;
- the implementation of our business model, and strategic plans for our business and current and future product candidates;
- our ability to raise capital on favorable terms, or at all, to support the continued growth of the business, and to continue as a going concern;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to maintain the listing of our common stock on Nasdaq;
- our ability to identify and consummate potential future strategic partnerships or business combinations;
- our expectations regarding the potential market size and the size of the patient population for nimacimab, if approved for commercial use;
- the clinical utility of nimacimab and its potential advantages over other therapeutic options;
- developments and projections relating to our competitors and our industry;
- current pending litigation matters, including the Cunning Lawsuit;
- the impact of new laws and regulations or amendments to existing laws and regulations in the United States and foreign countries; and

- the impact of global economic and political developments on our business, including rising inflation, volatile interest rates and capital market disruptions, economic sanctions and economic slowdowns or recessions or public health pandemics.

We operate in a rapidly changing environment and new risks emerge from time to time. As a result, it is not possible for our management to predict all risks, including the current geopolitical, global economic environment, the impacts of the high inflationary environment, and associated business disruptions such as delayed clinical trials, laboratory resources and supply chain limitations, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Annual Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. The forward-looking statements included in this Annual Report speak only as of the date hereof, and except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Annual Report to conform these statements to actual results or to changes in our expectations.

We may from time to time provide estimates, projections and other information concerning our industry, the general business environment, and the markets for certain diseases, including estimates regarding the potential size of those markets and the estimated incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events, circumstances or numbers, including actual disease prevalence rates and market size, may differ materially from the information reflected in this Annual Report. Unless otherwise expressly stated, we obtained this industry data, business information, market data, prevalence information and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources, in some cases applying our own assumptions and analysis that may, in the future, prove not to have been accurate.

Note regarding trademarks

“Skye,” "CBeyond" our logo and other trademarks, trade names or service marks of the Company appearing in this Annual Report, are the property of the Company. The other trademarks, trade names and service marks appearing in this Annual Report are the property of their respective owners. We do not intend our use or display of other companies’ trademarks, trade names or service marks to imply an endorsement or sponsorship of us by such companies, or any relationship with such companies. Solely for convenience, trademarks and trade names referred to in this Annual Report may appear without the ® or TM symbol.

Item 1. Business.

Overview

Skye Bioscience, Inc. is a clinical-stage biotechnology company pioneering next-generation molecules that modulate G-protein-coupled receptors ("GPCRs") to treat obesity, overweight, and metabolic disorders. Our lead candidate, nimacimab, is a peripherally restricted negative allosteric modulating antibody targeting cannabinoid receptor 1 ("CB1")—a key GPCR involved in metabolic regulation.

Except where the context indicates otherwise, references to "we," "us," "our," "Skye" or the" Company" refer to the company and its subsidiaries.

Strategy

We believe there is a growing demand for therapies that offer improved safety, efficacy, tolerability, quality of life and long-term health outcomes while addressing the limitations of currently approved treatments. Our objective is to drive innovation in the treatment landscape for obesity, overweight and metabolic disorders by developing potential first-in-class therapies that meet significant unmet medical needs globally.

Key elements of our strategy include:

- Advancing nimacimab through clinical development for the treatment of patients with obesity and overweight as a combination therapy and evaluating its potential as a standalone or second-line therapy.
- Expanding the clinical utility of nimacimab by exploring additional metabolic indications where inflammation and fibrosis contribute to disease progression, utilizing translational models to identify new therapeutic applications.
- Evaluating combination approaches by assessing nimacimab in combination with incretin-based therapies to enhance efficacy and patient outcomes in obesity and metabolic health management.
- Pursuing value add strategic partnerships and business development opportunities, including collaborations, licensing agreements, and other transactions to accelerate the clinical and commercial development of nimacimab.
- Developing next generation GPCR-targeting molecules designed to address metabolic disorders.
- Expanding our pipeline through in-licensing or acquisitions of complementary metabolic health technologies and product candidates that target GPCRs and align with our strategic vision.

Our Product Candidate

Nimacimab

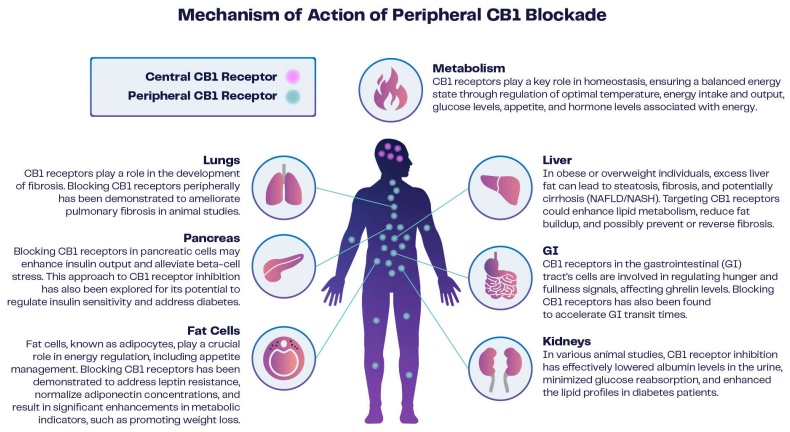
We completed the acquisition of Bird Rock Bio, Inc. (“Bird Rock”), a privately held, clinical-stage biotechnology company, in August 2023. Through this transaction, we acquired nimacimab, a humanized IgG4 negative allosteric modulating ("NAM") antibody that specifically binds to the CB1 receptor with no cross-reactivity to certain other GPCRs, including cannabinoid receptor 2 ("CB2").

Unmet Need and Market Opportunity

Obesity is a complex, heterogeneous, chronic, and progressive disease, which substantially affects health, quality of life and mortality. "Obesity" and "severe obesity" are defined by a body mass index ("BMI") of greater than 30 and 40 kg/m2, respectively, with abnormal or excessive fat accumulation. "Overweight" is defined by a BMI of greater than 25 kg/m2. Obesity and overweight states are characterized by a chronic energy surplus in which the body’s energy intake exceeds its energy expenditure and are often associated with excess and chronic inflammation of adipose and other tissues. Other stressors and environmental factors contribute to this chronic imbalance. Today, obesity is the fifth-leading risk factor cited by the World Health Organization ("WHO") for contributing as a primary cause of death globally. Based on estimates by the WHO, globally, obesity affected more than 890 million adults as of 2022, and we believe it has continued to increase in prevalence worldwide since the WHO declared a global obesity epidemic in 1997. In addition, the WHO estimates that 2.5 billion adults were overweight as of 2022. Current estimates by the World Obesity Atlas suggest that 54% of the global population will be overweight or obese by 2035, compared to 46% in 2025. In addition, it is estimated that 39% of, or 770 million, children between the ages of five and nineteen years of age will be overweight or obese by 2035 compared to 28% of, or 550 million, such children in 2025. Based on several analyst estimates, we believe this deeply rooted global health crisis could represent a total addressable market of more than $100 billion annually by 2030. Previous treatments for obesity have been limited by safety concerns and insufficient efficacy, which we believe hindered their success. However, incretin-based therapeutics have shown significant weight loss and positive cardiovascular effects in clinical studies. While glucagon-like peptide-1 ("GLP-1") receptor agonists have been effective in reducing overall body weight, this weight loss also includes, on average, an estimated 25-40% loss of lean muscle mass. Patients using GLP-1 therapies also face tolerability issues, particularly gastrointestinal discomfort, which can affect the duration of treatment and lead to high rates of discontinuation. Moreover, even for those patients who can tolerate therapy there are still up to 15% of these patients that lose less than 5% of weight at three months of treatment and are considered non-responders. Despite the remarkable efficacy and commercial success of GLP-1 therapies, we believe there is still potential to improve the quality and sustainability of weight loss regimens, as well as, help patients who can not tolerate or do not respond to GLP-1 therapies. We believe the combination of non-incretin mechanisms, such as nimacimab, with incretin therapies like GLP-1s could improve outcomes compared to solely using incretin therapies. Alternatively, we believe a non-incretin mechanism could be used as a follow-up to standard GLP-1 treatments or as an alternative for specific patient groups with obesity and overweight.

Role of CB1 in the Treatment of Obesity and Other Metabolic Conditions

The CB1 receptor is one of the most abundant receptors in the endocannabinoid system ("ECS"), playing a significant role both in the central nervous system ("CNS") and peripheral tissues. In the CNS, the CB1 receptors are involved in motor control, cognition, emotional regulation, and hunger cues. However, CB1 receptors are also highly prevalent in peripheral tissues, including the liver, kidney, adipose tissue (fat cells), pancreas, and gastrointestinal tract. Notably, the role of CB1 in peripheral tissues is crucial for metabolic regulation. In adipose tissue, for example, activation of CB1 receptors is closely linked to the promotion of fat storage, making it a key target for obesity-related therapies. In the kidney, CB1 signaling helps regulate blood flow, which is essential for waste filtration and maintaining electrolyte balance and blood pressure. In the liver, CB1 plays a critical role in regulating lipid metabolism and glucose homeostasis. Additionally, activation of CB1 receptors in the gastrointestinal tract influences the release of neurotransmitters and hormones that regulate appetite, gastric motility, and nutrient absorption. Given its widespread influence on metabolic processes in peripheral tissues, targeting CB1 outside the CNS represents a promising therapeutic strategy for improving metabolic health and addressing obesity.



Building on the diverse roles of CB1 receptors in peripheral tissues, the "CB1 axis" emerges as a critical pathway for metabolic regulation, linking the activation of CB1 receptors across various organs to the broader control of energy balance and metabolic function. The distribution and function of the CB1 axis provides a strong rationale to target this critical physiological system as a therapeutic to treat different pathological states. Moreover, dysregulation of the CB1 axis in peripheral tissues has been associated with metabolic disorders such as obesity and kidney disease. Recent research highlights that inhibiting CB1 outside the brain can influence leptin sensitivity and adipocyte signaling, directly impacting fat cell physiology. Activation of CB1 promotes fat accumulation and disrupts mitochondrial function in obesity models, whereas inhibiting CB1 enhances mitochondrial biogenesis. This metabolic adjustment results in weight loss through heightened energy expenditure, increased lipolysis, and fatty acid oxidation processes, particularly in brown adipose tissue.

CB1 Inhibition: Small Molecule Clinical Experience and New Approaches

It has been previously demonstrated that inhibiting the CB1 receptor can significantly reduce weight in patients with obesity. In 2006, Sanofi (formerly Sanofi-Aventis) developed a small molecule CB1 inverse agonist called rimonabant, which demonstrated 10% or greater weight loss after one year, in 25.2% of patients receiving 20 mg of rimonabant. Despite being approved by the European Medicines Agency, the drug was soon taken off the market due to severe adverse neuropsychiatric side effects, including suicidal ideation. Since rimonabant was taken off the market, a significant amount of research was conducted to better understand why rimonabant failed. Ultimately it was determined that rimonabant, a small molecule, readily entered the brain, resulting in severe adverse neuropsychiatric side effects.

A new generation of small molecule CB1 inhibitors are being developed with the aim of minimizing inhibition of CB1 receptors in the brain and maximizing exposure in the peripheral tissues. These new generation small molecule CB1 inverse agonists have been modified to discourage distribution in the CNS and brain by increasing the polarity of surface residues, which also impacts membranous trafficking and bioavailability. While these altered small molecules yield notable reductions in CNS distribution relative to non-biased small molecules such as rimonabant, its presence and significant CB1 occupancy in the brain has still been noted in chronic preclinical and clinical settings. Phase 2 data related to this new generation of small molecules resulted in dose-dependent mild to moderate adverse neuropsychiatric side effects, such as irritability, anxiety and sleep disturbances, confirming that these molecules continue to cross the blood-brain barrier when dosed at levels required to achieve desired levels of weight loss.

We believe that the safest and most effective way to inhibit CB1 is with a large-molecule approach to potentially eliminate safety concerns from the molecule penetrating the blood-brain barrier. We believe nimacimab, as a large molecule, has the potential to mitigate safety concerns associated with the CB1 class due to our ability to administer higher doses of nimacimab, without significant concentrations of nimacimab penetrating the blood-brain barrier.

Nimacimab Product Differentiation

Weight loss continues to be the primary endpoint to evaluate efficacy in patients with obesity and overweight. However, we recognize, through our engagement with key advisors and healthcare providers, that the obesity and overweight market is heterogeneous and that different patients may need different therapies to manage their condition(s). As these markets grow, we believe there is an increasing demand from healthcare providers for alternative therapies to treat obesity and other metabolic conditions, along with their associated comorbidities. While the current GLP-1 drugs are efficacious, we believe there is room to optimize dosing regimens, develop drugs with more favorable side effect profiles, and build upon the current mechanisms to re-establish healthy metabolic pathways.

The current incretin mimetic drugs approved for weight loss act primarily through caloric restriction by increasing GLP-1 in the gut and signaling to the CNS feelings of satiety or fullness. While caloric restriction is an effective way to manage weight loss, it has been shown that caloric restriction alone, without appropriate lifestyle intervention, will lead to loss of lean mass. For example, based on clinical trial data for semaglutide, a GLP-1 agonist, on average 25-40% of the weight loss results from the loss of lean mass (which can include both muscle and bone). In addition, up to 70% of patients experience gastrointestinal ("GI") side effects with semaglutide including nausea, vomiting, constipation and diarrhea, which can lead to discontinuation of treatment in some cases.

We believe nimacimab stands apart from GLP-1s and other incretin-based weight loss therapies because its primary mechanism goes beyond suppression of food intake. While peripheral CB1 inhibition can reduce elevated leptin levels as well as modulate appetite-regulating hormones to broadly blunt appetite, key additional drivers of weight loss include increased energy expenditure, fat metabolism, and insulin sensitivity as well as reduced inflammation. As a result, clinical data from this class of drugs have demonstrated not only weight loss but also lean mass preservation, improved insulin sensitivity, and reductions in cholesterol. Additionally, preclinical obesity models using CB1 inhibitors have shown improvements in hyperleptinemia, leptin sensitivity, and increased energy expenditure. This unique mechanism offers a potential alternative, and even complementary, approach to chronic weight management, broadening therapeutic options for patients with obesity and overweight.

Nimacimab's Differentiation Within the CB1 Class

Within the CB1 inhibitor class, we believe nimacimab is distinct from competing drug candidates primarily because it is a large-molecule antibody and has a distinct mechanism of noncompetitive inhibition that collectively confers several advantages over the small molecules in development.

1. **Enhanced Selectivity and Safety** - As an antibody, nimacimab exhibits high specificity for CB1, reducing the risk of off-target toxicity—a critical factor given the historical safety concerns with CB1 inhibition. Our Phase 1 and Phase 2a studies established the potential for nimacimab's favorable safety profile, with no observed neuropsychiatric adverse effects and excellent GI tolerability, a key differentiation from previous CB1-targeting drugs.

2. **Negative Allosteric Modulation** - Nimacimab functions as a negative allosteric modulator of CB1, which means it binds to a distinct area of CB1 'away' from the receptor's primary active site (the orthosteric site) and thus inhibits CB1 activity without any competition from the endogenous ligands (endocannabinoids). We believe this noncompetitive mode of action is distinct from small-molecule inhibitors, which target CB1 receptor's orthosteric site and require successful competition with endocannabinoids for receptor occupancy to inhibit CB1 signaling. We believe this can become critical as CB1 signaling is often overactive in metabolic diseases, and direct competition with an inhibitor that binds at the orthosteric site and competes with endocannabinoids for binding to the receptor may be insufficient in tissues with excessive CB1 activity. In such disease states, where both CB1 receptor density and endocannabinoid levels are elevated, orthosteric small molecules must outcompete high concentrations of endocannabinoids, which can negatively impact their Pharmacodynamic ("PD") profile and ultimately limit their efficacy.
3. **Inverse Agonism** - As described above, nimacimab is a noncompetitive inhibitor which we believe confers specific advantages. Additionally, nimacimab can inhibit CB1 without an agonist present in which case it can drive the opposite signaling of CB1 agonists such as promoting increased cAMP and reducing b-arrestin recruitment. Thus, nimacimab inhibits CB1 as both a noncompetitive antagonist and an inverse agonist.
4. **Superior Dosing and PK Profile** - Small-molecule CB1 inhibitors require daily oral dosing, which increases systemic exposure and potential toxicity risks. Nimacimab, with its 18-22 day half-life, supports once-monthly subcutaneous dosing, enhancing patient compliance while maintaining consistent receptor inhibition.
5. **Potential for Combination Therapies** - The antibody format opens opportunities for combinations with therapeutics targeting orthogonal and/or distinct mechanistic pathways using bi- or tri-specific bioconjugation approaches. Combining a more tolerable dose of a GLP-1 agonist (to drive caloric restriction) with a safe CB1 inhibition mechanism (to drive fat metabolism) could yield additive or even synergistic weight loss effects. Our Phase 2a study includes an exploratory arm evaluating the combination of Wegovy (semaglutide) with Nimacimab to assess this potential.

Summary of Preclinical Data

The CB1 pathway is clinically validated to drive weight loss and has many supporting studies that highlight peripheral mechanisms to promote productive metabolic changes, including weight loss. We endeavored to understand if nimacimab could drive weight loss using a diet-induced obesity ("DIO") mouse model. Since nimacimab does not cross-react with mouse CB1, a transgenic mouse was generated which targeted the murine CB1 ("mCB1") loci for insertion of human CB1 ("hCB1"). This targeted disruption of mCB1 for hCB1 knockin mice was confirmed genetically as well as functionally, as measured by productive CB1 signaling in a THC-induced hyperthermia model as well as the ability to generate obese mice with a high fat diet ("HFD") with similar kinetics and magnitude of weight gain. We found that the use of nimacimab in this mouse DIO model demonstrated the following:

- significant dose-dependent weight loss compared to vehicle;
- significant fat mass loss with lean mass preservation; and
- dose-dependent glycemic improvements

Furthermore, an additional preclinical mouse DIO study provided further evidence for the potential combination of nimacimab with incretins and demonstrated the potential durability of response with nimacimab as a monotherapy or maintenance therapy post-incretin treatment. This preclinical mouse DIO study demonstrated that at day 25 the combination of nimacimab and a suboptimal tirzepatide dose (3nmol/kg daily) yielded 44% vehicle-adjusted weight loss (29.6% weight loss). The combination outperformed either agent alone with nimacimab demonstrating 21.5% vehicle-adjusted weight loss (7.1% weight loss) and the suboptimal tirzepatide dose demonstrating 29.7% vehicle-adjusted weight loss (15.4% weight loss). The combination efficacy also exceeded an optimal dose of tirzepatide (10 nmol/kg), which resulted in 38.9% vehicle-adjusted weight loss (24.6% weight loss). The preclinical mouse DIO study also demonstrated that, when used as a monotherapy, nimacimab-driven weight loss persisted for about 20 days after treatment cessation, while mice treated with tirzepatide alone regained most of their lost weight within a week post-treatment. Lastly, the preclinical mouse DIO study demonstrated that when nimacimab alone was used after an initial tirzepatide or combination treatment in the preclinical mouse DIO mouse model, it reduced rebound weight gain in these groups of mice.

In addition to clinical data sets from monlunabant and rimonabant, we believe these DIO data support the hypothesis that peripheral CB1 inhibition is sufficient for weight loss while central CB1 inhibition is not required for metabolic improvements such as weight loss.

Nonclinical Data

Two Investigational New Drug Applications ("IND")-enabling nonclinical studies with nimacimab were completed in non-human primates, which demonstrated a strong safety profile with a no adverse effect level ("NOAEL") of 75 mg/kg with bi-weekly dosing for 26 weeks. In addition, nimacimab was shown in two independent non-human primate biodistribution studies to have almost no exposure in the brain (~0.02%), with multi-dose studies demonstrating no accumulation.

A 3-week subcutaneous injection toxicity study in cynomolgus monkeys was completed to determine the toxicity and toxicokinetic ("TK") profile of two dose levels of 25 mg/kg and 75 mg/kg of nimacimab versus a matching placebo, following two subcutaneous ("SC") injections two weeks apart. In this study, no mortality occurred and there were no effects noted on clinical signs, ophthalmology, electrocardiography, hematology, clinical chemistry, coagulation and urinalysis during the course of the study. There were no nimacimab effects noted on organ weights, and no nimacimab-related macroscopic or microscopic observations.

Subsequently, a repeat-dose toxicity study was conducted in cynomolgus monkeys at two dose levels of 40 mg/kg and 75 mg/kg nimacimab versus matching placebo to determine the toxicity and TK profile of nimacimab administered every two weeks over 26 weeks (13 total doses), and to assess the reversibility of any changes following an eight week recovery period. In this study, nimacimab was well-tolerated with results similar to the three week study with the only nimacimab-related macroscopic or microscopic observations consisting of reversible minimal to moderate inflammation at the injection site. In general, the TK of nimacimab indicates slow absorption from subcutaneous injection sites, low systemic clearance, a limited volume of distribution and a long terminal half-life. Based on the results of these studies, the NOAEL was considered to be the high dose of 75 mg/kg/dose.

Two non-human primate studies were conducted to further elucidate the CNS exposure of nimacimab. The first study dosed cynomolgus monkeys with nimacimab at 3mg/kg and 40 mg/kg and collected cerebral spinal fluid ("CSF") at multiple timepoints as a surrogate measure for CNS exposure. This data demonstrated that nimacimab has almost no exposure with little to no accumulation in the brain. A second study evaluated direct CNS exposure by performing a biodistribution study with radiolabeled nimacimab. Nimacimab was radiolabeled with 124-Iodine, and after confirmation of expected in vitro potency, administered intravenously ("IV") to 2 rhesus monkeys with positron emission tomography ("PET") scans were acquired for 30 minutes at 6 and 24 hours post-injection. Overall, animals showed lower signals in the heart, lung, liver, spleen and kidney at 24 hours compared to 6 hours. No significant uptake of nimacimab was observed in the brain at the time points studied.

Taken together, we believe these nonclinical studies demonstrate that nimacimab is safe, with an NOAEL of 75 mg/kg, and that very little, if any, nimacimab enters the CNS.

Clinical Development History of Nimacimab

Summary of Completed Phase 1 Studies

In June 2017, Bird Rock initiated a Phase 1b study. The purpose of the study was to evaluate the safety and tolerability of multiple doses of nimacimab after four weeks of dosing in subjects with non-alcoholic fatty liver disease ("NAFLD"), now known as metabolic-associated steatotic liver disease ("MASLD"). Secondary objectives included determination of pharmacokinetics of nimacimab for multiple doses and to determine levels of anti-drug antibodies ("ADA") after dosing with nimacimab. The study was carried out in subjects who had baseline MASLD. This was done to enable the preliminary assessment of biomarkers of liver disease with short term therapy. We believe the short duration of treatment, small number of patients in each cohort and lack of any dietary restrictions should be taken into account when considering the results.

In Part A of this study, 24 healthy volunteers were randomized to receive a single dose of either placebo or single ascending doses of nimacimab (0.6, 1.2 or 2.5 mg/kg). In Part B of this study, 82 patients with pre-diabetes or diabetes and MASLD were randomized to receive either placebo or multiple escalating doses of nimacimab (0.6, 1.2 or 2.5 mg/kg) once a week for four weeks. There were no deaths, serious adverse events ("SAEs") or treatment-emergent adverse events ("TEAEs") that lead to discontinuation. All TEAEs were graded as mild to moderate in intensity except for one severe TEAE (dizziness) in the nimacimab 0.6 mg/kg dose group determined to have not been related to study drug. The majority of TEAEs were not related to study drug and there was no apparent relationship between the dose level and the type, severity, or incidence of the TEAEs.

For all subjects at all doses, concentrations of nimacimab were quantifiable in serum by 0.5 hours after the first dose and remained quantifiable in most subjects through the last time point, day 67. Exposure to nimacimab as measured by AUC and C_{max} increased with increasing doses of nimacimab. At all dose levels, median T_{max} ranged from 0.5 to 2 hours and mean $t_{1/2}$ ranged from 18 to 22 days.

Immunogenicity was assessed in all subjects throughout the study. Only two subjects had consistently elevated titers over multiple time points of ADA. This data suggest that nimacimab has an overall low immunogenicity profile.

The placebo group in the Phase 1 study had an increase in weight while the treatment groups showed stable weight resulting in a numerical difference that represents an early trend for potential efficacy. Decreases in mean alanine transaminase ("ALT") and aspartate aminotransferase ("AST") were observed during the study in the active treatment groups, but not in the placebo group. Numeric decreases in ELF score and statistically significant reduction in hyaluronic acid ("HA") was observed in the 1.2 mg/kg dose group compared to placebo (p=0.02). Assessment of serum lipids indicated a dose-dependent trend towards reduction of low-density lipoprotein cholesterol (LDL-c) starting from Day 29; on Day 67 there was a mean 8.9 mg/dL decrease in LDL-c in the 2.5 mg/kg dose group compared with a mean 8.3 mg/dL increase in the placebo group (p=0.0073). No effect was observed in total cholesterol, high-density lipoprotein cholesterol (HDL-c), and triglycerides. No significant treatment effect was observed on liver fat percentage, de-novo lipogenesis, inflammatory biomarkers and OGTT test.

Full study data was presented at the European Association for the Study of Diabetes ("EASD") Annual Meeting in September 2025.

Summary of Phase 2a Study

In October 2025, we announced the results from our CBeyond Phase 2a proof-of-concept clinical trial of nimacimab administered as a subcutaneous injectable for the treatment of obesity and overweight in the United States. CBeyond is a randomized, placebo- and active-controlled, double-blind Phase 2a trial that enrolled 136 adults with obesity or overweight, including individuals with a BMI ≥27 kg/m² with at least one comorbidity. Patients were randomized across four arms, 2:2:1:1 to arms with weekly nimacimab 200 mg subcutaneously, placebo, nimacimab 200 mg plus semaglutide (Wegovy®), or placebo plus semaglutide, and were dosed weekly for 26 weeks. Patients not participating in a 26-week extension were monitored for 13 weeks post-treatment. We reported the following 26 week data from the CBeyond Phase 2a study :

- The nimacimab monotherapy arm did not achieve the primary endpoint of weight loss compared to placebo (-1.52% vs. -0.26 for placebo, mITT). Preliminary pharmacokinetic analysis suggested an association between exposure and response, indicating that the 200 mg, subcutaneous weekly dose was suboptimal as a monotherapy.
- At the tested dose and exposure levels, nimacimab 200 mg demonstrated a favorable safety profile with placebo-like tolerability. In combination with semaglutide, there was no increase in gastrointestinal (GI) adverse events. Importantly, there were no increases in neuropsychiatric adverse events reported resulting from treatment with nimacimab.
- In the combination arm, nimacimab 200 mg, subcutaneous weekly dose plus semaglutide demonstrated a clinically meaningful magnitude of weight loss compared to semaglutide alone (-13.2% vs -10.25%, p=0.0372, mITT), with no plateau being observed through Week 26. In the combination arm, 100% of patients achieved greater than 5% weight loss (vs. 85% with semaglutide alone) and 67% achieved greater than 10% weight loss (vs. 50% with semaglutide alone) based on the per protocol analysis. This finding supports potential further studies to evaluate combinations of nimacimab and incretin-based therapies, like semaglutide or tirzepatide. Other findings in the combination arm included:
    - Nimacimab plus semaglutide showed a change of -11.26cm (1.16cm) in waist circumference versus -8.09cm (1.2cm) for semaglutide alone, resulting in a difference of -3.17cm (1.59cm) (p=0.0492, using least-squares mean (LSM)).
    - An improvement in lean mass to fat mass ratio was observed at week 26 when comparing the nimacimab plus semaglutide combination arm to the placebo arm (0.26 vs. 0.02, p <0.0001), and the combination arm compared to semaglutide alone (0.26 vs. 0.13, p = 0.0126).
    - A decrease in rebound weight gain in an analysis of participants 12 weeks post-treatment when nimacimab 200 mg (subcutaneous, weekly) was combined with semaglutide when compared to semaglutide alone (17.8% versus 37.3% weight rebound). Moreover, at 12 weeks post-treatment, the nimacimab plus semaglutide group maintained significant weight loss compared to the placebo group (p=0.006), while the semaglutide alone group lost significance over the placebo group (p=0.12) and followed a trajectory of rebound weight gain consistent with previously reported data (Wilding et al., 2022, STEP-1 Trial Extension), which demonstrated that patients will gain a majority of weight back within 1-year of stopping treatment with semaglutide.

Topline data from our CBeyond Phase 2a study was presented at ObesityWeek medical conference in November 2025.

Summary of Phase 2a Extension Study

Patients who completed 26 weeks of treatment in the Phase 2a study were eligible to enroll in a 26-week extension for a potential full treatment duration of 52 weeks with a 13-week follow-up period. A total of 43 patients were enrolled, with 19 and 24 patients in the combination and monotherapy cohorts, respectively. In the combination arms, continued with blinded treatment with nimacimab or placebo and continued receiving semaglutide (Wegovy®). Patients in the monotherapy arm received nimacimab 300 mg during the extension.

In February 2026, the Company reported the following interim results from the combination cohort of its Phase 2a extension study:

- 19 participants in the combination cohorts completed week 26 were eligible for, and enrolled in the extension study, which continued in a blinded manner for 26 weeks, maintaining their original treatment assignment (10 nimacimab plus semaglutide; 9 placebo plus semaglutide). An additional 22 participants completed week 26 and were either ineligible for the extension or chose not to join the extension study and continued on post-treatment follow-up (11 nimacimab plus semaglutide; 11 placebo plus semaglutide).
- Of the 10 participants in the nimacimab plus semaglutide arm who joined the extension study, the mean weight loss at 26 weeks was 14.4%. 7 participants completed the additional 26 weeks of treatment and lost an additional 7.9% of weight, resulting in a mean weight loss of 22.3% after 52 weeks of treatment. According to initial results in this limited cohort, the combination therapy remained safe and well tolerated. No SAEs or AESIs were reported during the extension period.
- Of the 9 participants in the placebo plus semaglutide arm that joined the extension study, mean weight loss at 26 weeks was -13.9%. 7 participants completed treatment of the additional 26 weeks and lost an additional -5.8% of weight during the extension period, resulting in a mean weight loss of -19.7% after 52 weeks of treatment.

Full topline reporting of the CBeyond Phase 2a extension data including nimacimab monotherapy data and 13-week off-therapy follow-up is expected to take place in the third quarter of 2026.

Clinical Development Plan

In March 2026, we initiated an expansion study (Part C) of the CBeyond Phase 2a trial to assess preliminary safety and pharmacokinetic (PK) profile of nimacimab administered intravenously (IV). The expansion study will comprise two cohorts of nimacimab monotherapy (400 mg IV and 600 mg IV) compared to placebo administered weekly over 15 weeks (16 doses), with a 12 week follow up period, to generate preliminary monotherapy safety, PK, and exploratory efficacy data. Within each dose cohort, 8 participants will be randomized in a 3:1 ratio to nimacimab (n=6) or placebo (n=2). We expect to report topline data from the expansion study in the fourth quarter of 2026.

We have received comments from the agency regarding our Type C meeting request in which they responded to our proposed Phase 2b clinical trial design, we intend to use data from the CBeyond trial, including the CBeyond expansion study (Part C), to inform the design of a potential Phase 2b study and potential registration path for nimacimab as a combination therapy with GLP-1s. Key design elements under evaluation include patient selection, dose selection, treatment duration, and endpoints. Final trial design and timing remain subject to ongoing data analysis, regulatory feedback and capital considerations.

Competition

The biopharmaceutical and pharmaceutical industries are intensely competitive and characterized by rapid technological progress. In general, competition among pharmaceutical products is based in part on product efficacy, safety, reliability, availability, price and patent position. An important factor is the relative timing of the market introduction of our products and our competitors' products. Accordingly, the speed with which we can develop products, complete clinical trials and approval processes and supply commercial quantities of the products to the market impacts our competitiveness. Our competitive position also depends upon our ability to show differentiation with a product that is either more efficacious, particularly in the relevant target populations, offers a better safety or tolerability profile, is less expensive or quicker to manufacture, or represents a combination of these advantages. We also depend upon our ability to attract and retain qualified personnel, obtain patent protection or otherwise develop proprietary products or processes and secure sufficient capital resources for the often substantial period between technological conception and commercial sale. While we believe that our knowledge, experience and scientific resources provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others.

If nimacimab is approved for the indications for which we expect to conduct clinical studies, it will compete with the foregoing therapies and currently marketed drugs, as well as any drugs potentially in development. It is also possible that we will face competition from other pharmaceutical approaches as well as other types of therapies. The key competitive factors affecting the success of our program, if approved, is likely to be its efficacy, safety, differentiation, convenience, price, level of generic competition, and availability of reimbursement. Despite significant biopharmaceutical industry investment, no therapy targeting CB1 has been approved for the treatment of obesity in the US.

Large and established pharmaceutical companies are developing GLP-1 agonists or combinations with other incretin-mimetics, which compete in the same market as our product candidates. These companies generally have greater experience and resources to support their research and development efforts, conduct testing and clinical trials, obtain regulatory approvals to market products, manufacture such products on a broad scale and market approved products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development and have collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the products that we develop obsolete. We also face competition from smaller companies who, like us, rely on investors to fund research and development and compete for co-development and licensing opportunities from large and established pharmaceutical companies. Regarding the use of nimacimab to target peripheral inhibition of CB1 for the treatment of obesity and metabolic conditions, our direct competition includes monlunabant, a small molecule CB1 receptor inverse agonist.

Other companies are targeting proteins associated muscle preservation and growth with the aim of complementing the GLP-1 agonists by improving lean mass preservation. While many of these drugs are in the same stage of development, they have a different and potentially more difficult regulatory path than nimacimab. Based on the recent FDA guidance, companies who wish to receive marketing approval for lean mass preservation must obtain acceptance from the FDA as to the appropriate primary endpoints, while the FDA guidance for drugs approved for weight loss in the overweight and obese population remains unchanged and clearly defined.

The development and commercialization of therapies for the treatment of obesity and overweight is highly competitive. Our product candidate, nimacimab, if approved, will face significant competition, including from well-established, currently marketed therapies that have been developed by large, well-known pharmaceutical companies, and our failure to demonstrate a meaningful improvement to the existing standard of care may prevent us from achieving significant market penetration. In particular, there is intense competition in the obesity and overweight field, especially with the advent of GLP-1 RAs, such as Wegovy, marketed by Novo Nordisk, and Zepbound, marketed by Eli Lilly. In addition to injectable therapies for overweight and obesity, Wegovy became the first FDA approved oral GLP-1 receptor agonist in December 2025 and other oral therapies are in development for treating overweight and obesity, including those being development by Eli Lilly, Structure Therapeutics, and Viking Therapeutics. There are numerous other companies that have commercialized or are developing treatments for obesity and overweight that we will compete with. Competitors to nimacimab that are targeting peripheral inhibition of CB1 for the treatment of obesity and metabolic conditions include Novo Nordisk and their development effort of monlunabant. We face competition from these companies and other major pharmaceutical and biotechnology companies, including specialty pharmaceutical companies, academic institutions, governmental agencies and public and private research institutions, among others. Refer to "*Risks Related to Commercialization — We face significant competition from entities that have made substantial investments into developing novel treatment for patients with obesity and overweight, including large pharmaceutical companies with approved therapies in our current indications, and biopharmaceutical, specialty pharmaceutical and biotechnology companies developing novel treatments and technology platforms. If the companies develop competing technologies or product candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize products may be adversely affected*" in our Risk Factors section for additional information.

Manufacturing

We do not own or operate manufacturing facilities and we rely on third-party contract manufacturing organizations (“CMOs”) to supply nimacimab for our pre-clinical and clinical studies. Nimacimab, a monoclonal antibody, is produced under current good manufacturing practices (“cGMP”) through recombinant DNA technology, leveraging established upstream cell culture processes and downstream purification methods. The resulting drug substance is formulated and filled into pre-filled syringes by our third-party partners.

To meet anticipated clinical and commercial needs, we are making a substantial investment in our manufacturing infrastructure through these CMOs. Key activities include:

- **Formulation Optimization:** We are evaluating multiple formulations aimed at improving patient convenience.
- **Process Optimization:** We continue to optimize our manufacturing to evaluate modifications to both our upstream and downstream processes to improve product yield. The activities are aligned with our goals to establish a commercial manufacturing process that is reliable and repeatable at large commercial scales.
- **Device Strategy:** We are exploring new delivery platforms for nimacimab, with a view towards improving patient experience and adherence in later-stage clinical studies and eventual commercial distribution.

We believe that our collaborative approach with leading CMOs and other partners involved in our chemistry, manufacturing and controls ("CMC") operations, positions us to reliably meet future clinical and commercial demand for nimacimab and further optimize its potential for the treatment of obesity, overweight, and related metabolic disorders.

Halozyme License Agreement

In December 2025, the Company entered into a Non-exclusive Global Collaboration and License Agreement (the “Halozyme License Agreement”) with Halozyme, Inc. (“Halozyme”).

Under the terms of the Halozyme License Agreement, Halozyme granted the Company a non-exclusive license to Halozyme’s ENHANZE® drug delivery technology for the development of a subcutaneous co-formulation with nimacimab (such combination, the “Product”). Halozyme will also be the Company’s exclusive supplier of clinical and commercial supplies of the active pharmaceutical ingredient ("API") for Halozyme’s rHuPH20 bulk drug product.

Among other considerations, the Company will make milestone payments to Halozyme tied to achievement of certain development and commercialization milestone events with respect to the Product, as well as milestone payments based on achievement of certain net sales levels of the Product. The Company will also make mid-single digit royalty payments based on worldwide net sales of the Product. To date, none of such milestones has been achieved.

The Halozyme License Agreement became effective in December 2025 and, unless earlier terminated, will continue until the expiration of the royalty term for the applicable product in each country, which begins upon the first commercial sale of the product in such country and continues until the last valid patient claim covering the product in that country or the length of time specified in the Halozyme License Agreement. The Halozyme License Agreement also includes customary termination rights, representations and warranties, covenants and indemnification obligations for a transaction of this nature.

Intellectual Property

The success of our product candidates will depend in large part on our ability to obtain and maintain patent and other legal protection for the proprietary technology, inventions and improvements we consider important to our business, prosecute our patent applications and defend any issued patents we obtain, preserve the confidentiality of our trade secrets, and operate without infringing the patents and proprietary rights of third parties. We strive to protect the proprietary technologies that we believe are important to our business, including seeking and maintaining patent protection intended to cover the compositions of matter of our product candidates, their methods of use, related technologies, and other inventions that are important to our business. We employ a comprehensive approach to intellectual property protection and obtaining patent protection is not the only method that we utilize to protect our proprietary rights and technologies. We also rely upon trade secrets and know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position. We seek to protect our proprietary information in part using confidentiality agreements with our collaborators, scientific advisors, employees and consultants, and invention assignment agreements with our employees and selected consultants, scientific advisors and collaborators. The confidentiality agreements are designed to protect our proprietary information and, in the case of agreements or clauses requiring invention assignment, to grant us ownership of technologies that are developed through a relationship with a third party.

As of March 1, 2026, we owned three granted U.S. patents, 30 granted foreign patents, including granted patents in Europe, Japan, Korea and China, as well as other commercially relevant jurisdictions, and 10 pending U.S. and foreign patent applications directed to the compositions of matter for the nimacimab antibody and molecular variants, and to methods of treatment and uses of nimacimab and its variants for treating a number of diseases responsive to the modulation of the CB1 receptor, including obesity and related metabolic conditions. The patents, and, if issued, the patent(s) resulting from the pending patent applications will expire between 2035 and 2036, excluding any potential available patent term adjustment or patent term extension.

The use of nimacimab in therapeutic doses and methods for treating obesity and weight related comorbidities is further covered in two international (PCT) patent applications owned by us and from which we expect to file U.S. and other national-phase patent applications in commercially relevant jurisdictions. If issued, the patent(s) resulting from the pending applications have an expiration date of no earlier than 2045, excluding any potential patent term adjustment or patent term extension.

The use of nimacimab in a method of predicting whether a patient is at risk for developing Fast Progressing Renal Disease ("FPRD") and treating patients to avoid such risks is further covered in pending applications in the United States, Europe, Japan and Korea, as well as other commercially relevant jurisdictions. These claims are directed towards methods of diagnosing FPRD and towards treatment of patients suffering from FPRD with nimacimab. If issued, the patent(s) resulting from the pending application have an expiration date of no earlier than 2043, excluding any potential patent term adjustment or patent term extension.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries, extensively regulate, among other things, the research, development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, import and export of pharmaceutical products such as those we are developing.

The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources. A failure to comply with such laws and regulations or prevail in any enforcement action or litigation related to noncompliance could have a material adverse impact on our business, financial condition and results of operations and could cause the market value of our common stock to decline.

Review and approval of drugs and biologics in the United States

In the United States, the Food and Drug Administration ("FDA") regulates drugs under the Federal Food, Drug and Cosmetic Act (the "FDCA"), and its implementing regulations, and regulates biologics under the FDCA, the Public Health Service Act (the "PHSA"), and their implementing regulations. The process required by the FDA before new drug and biologic product candidates may be marketed in the United States generally involves the following:

- completion of nonclinical or preclinical laboratory tests and formulation studies conducted in accordance with Good Laboratory Practice regulations ("GLPs"), and other applicable regulations, which studies can include animal studies;
- 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 site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice regulations ("GCPs") to evaluate the safety and effectiveness of a proposed drug candidate, and the safety, purity and potency of a proposed biological product candidate, for its intended use;
- preparation and submission to the FDA of a New Drug Application ("NDA"), for a drug or a Biologics License Application ("BLA") for a biologic, after completion of all pivotal trials;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug or biologic is produced to assess compliance with current Good Manufacturing Practice requirements ("cGMPs"), to assure that the facilities, methods and controls are adequate to preserve the product’s identity, strength, quality and purity;
- satisfactory completion of potential inspection of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of the NDA or BLA to permit commercial marketing of the product for particular indications for use in the United States.

Once a product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests, which can include animal studies, include laboratory evaluations of product chemistry, toxicity and formulation. An IND sponsor must submit, among other things, the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans. An IND will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the trial includes an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the IND on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns or non-compliance with FDA requirements, in which case clinical trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted. The FDA may also place a trial on a partial clinical hold. A partial clinical hold is a delay or suspension of only part of the clinical work requested or ongoing under the IND. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation (or full investigation in the case of a partial clinical hold) may only begin or resume after the FDA has notified the sponsor that the investigation may proceed.

Clinical trials involve the administration of the investigational product to humans under the supervision of qualified investigators in accordance with GCP requirements. This includes the requirement that all research subjects/patients provide their informed consent in writing for their participation in any clinical trial. Clinical trials must be conducted under protocols detailing, among other things, the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol for each clinical trial must be submitted to the FDA as part of the IND, and a separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs or biologics, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information.

Furthermore, an independent IRB or ethics committee at each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB regulations. The FDA or the sponsor may suspend 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 investigational product has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. There are also requirements governing the registration of certain clinical trials and reporting of clinical trial results to public registries, including clinicaltrials.gov.

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

- **Phase 1**: The product candidate is initially introduced into healthy human subjects or, in certain indications, patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine maximal dosage.
- **Phase 2**: The product candidate is administered to a limited patient population with a specified disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy and safety of the product candidate for specific targeted diseases, and to determine dosage tolerance and optimal dosage.
- **Phase 3**: The product candidate is administered to the established patient population expected to benefit based upon the risk/benefit profile. Generally, this phase of studies are conducted at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial regulatory 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 or BLA.

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

NDA and BLA review and approval process

Assuming successful completion of all required testing in accordance with applicable regulatory requirements, the results of the product development, including among other things, results from nonclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for one or more indications. The NDA or BLA must include all relevant data available from preclinical and clinical studies, including negative or ambiguous results as well as positive findings, among other things. The submission of an NDA or BLA requires payment of a substantial user fee to the FDA, and the sponsor of an approved NDA or BLA is also subject to an annual program fee. A waiver of certain user fees may be obtained under certain limited circumstances.

The FDA conducts a preliminary review of all NDAs and BLAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may refuse to file any NDA or BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the NDA or BLA must be resubmitted with the additional information requested before FDA will review the application. Once filed, the FDA reviews a BLA to determine, among other things, whether the product is safe, pure and potent for its intended use, and an NDA to determine, among other things, whether the drug is safe and effective for its intended use. As part of the NDA and BLA review, the FDA also evaluates whether the manufacturing of the products is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity.

Under the Prescription Drug User Fee Act ("PDUFA"), guidelines that are currently in effect, the FDA has a goal of reviewing and responding to a standard submission within ten months from the date of the "filing" of an original NDA or BLA to review and act on the submission. This review typically takes twelve months from the date the NDA or BLA is submitted to the FDA because the FDA has approximately two months to make a "filing" decision. The FDA does not always meet its PDUFA goal dates, however, and the review process can be significantly extended by the FDA requests for additional information or clarification, the applicant's submission of additional information, or other reasons.

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

During its review of an NDA or BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. Additionally, within the review period and before approving a BLA or NDA, the FDA will likely inspect one or more clinical trial sites to assure compliance with GCPs and the integrity of the clinical data submitted. After evaluating the NDA or BLA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter ("CRL"). A CRL generally contains a statement of specific conditions that must be met to secure final approval of the NDA or BLA and may require additional clinical or nonclinical testing in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter for the NDA or BLA. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

If the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product's labeling; require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the product's safety or effectiveness or safety, purity, and potency after approval; require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including a risk evaluation and mitigation strategy ("REMS"), which can materially affect the potential market and profitability of the product. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS in connection with the application. The FDA will not approve the application without an approved REMS, if one is required. The REMS could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of commercial products.

In addition, the Pediatric Research Equity Act ("PREA") requires a sponsor to conduct pediatric clinical trials for most biologics and drugs. Under PREA, original NDAs and BLAs (and certain supplements) for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must contain a pediatric assessment or reports on the molecularly targeted pediatric cancer investigation, unless the sponsor has received a deferral or waiver or an exception applies. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and support dosing and administration for each pediatric subpopulation for which the product is deemed safe and effective. The sponsor may request, or the FDA may grant, a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug or biologic is ready for approval for use in adults before pediatric clinical trials are complete or that additional data needs to be collected before the pediatric clinical trial begins.

Expedited development and review programs

The FDA has a number of programs intended to expedite the development or review of a marketing application for an investigational product. For example, the fast track designation program is intended to expedite or facilitate the process for developing and reviewing product candidates that meet certain criteria. Specifically, investigational drugs and biologics are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a marketing application is submitted, the application may be eligible for priority review. With regard to a fast track product candidate, the FDA may consider for review sections of the application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the applications and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any product candidate submitted to the FDA for approval, including a product candidate with a fast track designation or breakthrough designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. An NDA or BLA is eligible for priority review if the product candidate is designed to treat a serious condition, and if approved, would provide a significant improvement in safety or efficacy compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an NDA or BLA designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of original NDAs or BLAs under its current PDUFA review goals.

In addition, a product candidate may be eligible for accelerated approval. A product candidate intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product candidate has 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, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA generally requires that a sponsor of a biologic receiving accelerated approval perform adequate and well-controlled confirmatory clinical trials, and may require that such confirmatory trials be underway prior to granting accelerated approval. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required confirmatory trials in a timely manner or if such trials fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition of accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast track designation, breakthrough therapy designation, priority review, and accelerated approval do not change the standards for approval, but may expedite the development or approval process. Even if a product candidate 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

Drugs and biologics manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion, and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to FDA review and approval prior to implementation. There also are continuing annual program fees for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

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

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

In addition, the FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs and biologics may be promoted only for the approved indications and in accordance with the provisions of the approved label. 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. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may legally prescribe commercially-available products for uses that are not described in the product's labeling and that differ from those tested by use and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of such physicians in their choice of treatments. The FDA does, however, restrict manufacturers' communications on the subject of off-label use of their products.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act ("PDMA"), which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Combination Products

Certain of our product candidates, may be comprised of components, such as drug components and biologic components, that would normally be regulated under different regulatory pathways, regulatory authorities, and frequently by different centers at the FDA. In addition, our injectable product candidates are being developed together with an injector device, which will render them combination products with a device component. We also are focusing our development efforts on at least one product candidate as a therapy intended to be used in combination with GLP-1 receptor agonists (and potentially other anti-obesity therapies). Even where such therapies are not physically combined or co-packaged with our product candidates, seeking approval for use in combination may require additional clinical and nonclinical evidence and could increase development time, cost, and regulatory risk.

Specifically, under regulations issued by the FDA, a combination product may include:

- a product comprised of two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and composed of drug and device products, device and biological products, biological and drug products or biological products, drug products and device products;
- a drug, or device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an individually specified drug, or device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product, the labeling of the other product would need to be updated (e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose); or
- an investigational drug, or device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

Under the FDCA and its implementing regulations, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The designation of a lead center generally eliminates the need to receive approvals from more than one FDA center for combination products, although it does not preclude consultations by the lead center with another FDA center. The determination of which center will be the lead center is based on the “primary mode of action” of the combination product. The FDA has established an Office of Combination Products to address issues regarding combination products and provide more certainty to the regulatory review process. This office is responsible for developing guidance and regulations to clarify the regulation of combination products, and for assigning the FDA center that will have primary jurisdiction for review of a combination product where the jurisdiction is unclear or in dispute.

Following approval of a combination product, each component of a combination product retains its regulatory status (as a biologic, drug or device, for example) and is subject to the requirements established by the FDA for that type of component. Combination products require coordination within the FDA for review of each of their components (e.g., drug, device and/or biologic components) that would ordinarily require review by different FDA centers if authorized as standalone products, and this coordination may result in additional delays due to regulatory timing constraints and uncertainties in the product development and approval process.

A combination product candidate with a biologic primary mode of action generally would be reviewed and approved pursuant to a BLA. However, the applicable approval pathway for a product candidate may be a BLA or an NDA, depending on FDA’s determination of, among other things, the product’s primary mode of action and constituent parts, and we cannot predict with certainty how FDA will classify any of our product candidates. In reviewing the BLA for such a product, however, FDA reviewers in the biologic center could consult with their counterparts in the drug or device centers to ensure that the drug and device component of the combination product candidate, as applicable, met all requirements applicable to its category. In addition, under FDA regulations, combination products are subject to the cGMP requirements applicable to each component within the combination. We believe our combination product candidates are likely to be reviewed by the FDA under a BLA.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of our current product candidates and any future product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly referred to as the "Hatch Waxman Amendments"). The Hatch Waxman Amendments permit restoration of the patent term 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 and the submission date of a BLA plus the time between the submission date of a

BLA 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 U.S. Patent and Trademark Office ("PTO"), 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 BLA.

An abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009. This amendment to the PHSA, in part, attempts to minimize duplicative testing. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch.

A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. “First licensure” typically means the initial date the particular product at issue was licensed in the U.S. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

Pediatric exclusivity is another type of regulatory market exclusivity in the U.S. Pediatric exclusivity, if granted, adds six months to existing regulatory exclusivity periods for all formulations, dosage forms, and indications of the biologic. This six-month exclusivity may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA issued “Written Request” for such a trial.

Federal and State Fraud and Abuse, Data Privacy and Security Laws and Regulations

In addition to FDA restrictions on marketing of pharmaceutical products, federal and state fraud and abuse laws restrict business practices in the pharmaceutical industry. These laws include anti-kickback and false claims laws and regulations as well as data privacy and security laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term “remuneration” has been broadly interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exemptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not meet the requirements of a statutory or regulatory exception or safe harbor. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. In addition, 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 federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. A violation of the federal Anti-Kickback Statute may also constitute a false or fraudulent claim for purposes of the civil False Claims Act.

Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-covered, uses. In addition, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

The federal False Claims Act also created federal criminal statutes that prohibit knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the 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.

Pharmaceutical companies are also subject to the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other health care providers. The Patient Protection and Affordable Care Act, as amended by the ACA, signed into law on March 2010, created new federal requirements for reporting, by applicable manufacturers of covered drugs, payments and other transfers of value to physicians and teaching hospitals. Applicable manufacturers are also required to report annually to the government certain ownership and investment interests held by physicians and their immediate family members. In addition, certain states require implementation of commercial compliance programs and compliance with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, impose restrictions on marketing practices, and/or tracking and reporting of gifts, compensation and other remuneration or items of value provided to physicians and other health care professionals and entities.

We may also be subject to data privacy and security obligations, including federal and state laws related to the privacy and security of personal information. The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and its implementing regulations (the "HIPAA Rules") imposes specified requirements relating to the privacy, security and transmission of protected health information ("PHI") and may apply to certain of the information we process. Among other things, HITECH makes HIPAA's security and certain of its privacy requirements directly applicable to "business associates," defined as independent contractors or agents of covered entities, or other business associates, that create, receive, maintain, obtain, or transmit PHI in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same requirements, thus complicating compliance efforts.

To the extent that any of our product candidates, once approved, are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals.

The shifting commercial compliance environment and the need to build and maintain robust systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may violate one or more of the requirements. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Coverage and reimbursement

Successful sales of our product candidates in the U.S. market, if approved, will depend, in part, on the extent to which our drugs will be eligible for adequate reimbursement by third-party payors, such as government health programs, such as Medicare and Medicaid, and private health insurance (including managed care plans). Patients generally rely on such third-party payors to reimburse all or part of the costs associated with their prescriptions and therefore adequate coverage and reimbursement from such third-party payors are critical to new and ongoing product acceptance. Coverage and reimbursement policies for drug products can differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for drug products among third-party payors in the United States. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a return on our investment. There may be significant delays in obtaining coverage and reimbursement as the process of determining coverage and reimbursement is often time consuming and costly. Further, third-party payors are increasingly reducing reimbursements for medical drugs and services and implementing measures to control utilization of drugs such as requiring prior authorization or step therapy for coverage, among other things. For products administered under the supervision of a physician or other healthcare professional, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used or delivered may not be available, which may impact physician utilization.

Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic drugs. Adoption or expansion of price controls and cost-containment measures could further limit our net revenue and results. Decreases in third-party payor reimbursement for our product candidates, if approved, or a decision by a third-party payor to not cover our product candidates could have a material adverse effect on our sales, results of operations and financial condition.

General regulatory cost control measures may also affect reimbursement for our products. If we obtain approval to market a product candidate in the United States, we may be subject to spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs and/or any significant taxes or fees.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the Centers for Medicare and Medicaid Services ("CMS"), an agency within the Department of Health and Human Services ("HHS"), determines whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree.

Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

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

Healthcare reform

The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs to limit the growth healthcare costs, including price-controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs.

For example, in March 2010, the Affordable Care Act, or ACA, was enacted in the United States and substantially changed the way healthcare is financed by both the government and private insurers. The ACA contains provisions that may reduce the profitability of drug products. Among other things, the ACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expanded eligibility criteria for Medicaid programs; expanded the entities eligible for discounts under the 340B drug pricing program; and increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program. Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminated the statutory Medicaid drug rebate cap, for single source and innovator multiple source drugs, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price. Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries, presidential executive orders and proposed and enacted federal and state legislation and regulations designed to, among other things, reduce the cost of prescription drugs under Medicare, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products.

Most recently, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA"), into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (effective January 1, 2025). The IRA permits the Secretary of the Department of Health and Human Services, or HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs.

Existing healthcare reform measures, as well as the implementation of additional cost containment measures or other reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

Foreign Regulation

In order to market any product outside of the United States, we must comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales and distribution of our products. While our management and many of our consultants are familiar with and have been responsible for gaining marketing approval in many countries, we have not reviewed the specific regulations in countries outside of the United States.

Employees & Human Capital Resources

As of March 9, 2026, we have a total of 12 full-time employees, four of whom hold a Ph.D or MD degree. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationships with our employees to be good. In addition, we rely on a number of consultants to assist us.

We strive to foster collaborative, communicative and flexible environment so that our employees feel supported in the workplace. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees. The principal purposes of our benefits and incentive plans are to attract, retain and motivate our employees, consultants and directors through the granting of stock-based compensation awards, providing competitive benefits packages and providing cash-based performance bonuses, 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 anticipate that we will need to hire additional employees or independent contractors for our continued development efforts. We also intend to utilize independent contractors and outsourced services, such as contract research organizations ("CROs") and third party manufacturers, where possible and appropriate.

Corporate Information

We were incorporated in the State of Nevada on March 16, 2011.

Our principal executive office is located at 11250 El Camino Real, Suite 100, San Diego, CA 92130. Our telephone number is (858) 410-0266.

Our website, which is located at http://www.skyebioscience.com, describes our company and our management and provides information about our technology and product candidates. Information contained on our website is not incorporated by reference into, and should not be considered a part of this Annual Report.

Available Information

Our filings, including Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments submitted under Sections 13(a) or 15(d) of the Exchange Act are accessible at no cost on our company website at www.skyebioscience.com as soon as reasonably practicable after we electronically file such material with or furnish it to the Securities and Exchange Commission ("SEC"). Additionally, these documents are retrievable from the SEC's website (www.sec.gov). We use our investor relations website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD. Investors should monitor such website, in addition to our press releases, SEC filings and public conference calls and webcasts. Information relating to our corporate governance materials, such as our corporate governance guidelines and committee charters, are also accessible on our investor relations webpage under "Corporate Governance." It's important to note that the content of our websites is not intended for inclusion by reference in our filings with the SEC, and any website references serve as inactive textual mentions only.

RISK FACTORS

Item 1A. Risk Factors.

You should consider carefully the following risk factors, together with the other information contained in this Annual Report, including our consolidated financial statements and the related notes and "Management Discussion and Analysis of Financial Condition and Results of Operations," before making a decision to purchase or sell shares of our common stock. We cannot assure you that any of the events discussed in the risk factors below will not occur. If any of the following events actually occur, our business, operating results, prospects or financial condition could be materially and adversely affected. This could cause the trading price of our common stock to decline and you may lose all or part of your investment. The risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business operations or financial condition.

Risk Factor Summary

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

- We have a limited operating history, a history of losses and expect to incur additional losses in the future.
- We have incurred significant losses, have limited cash on hand and our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.
- We depend heavily on the ability to advance nimacimab through clinical development.
- We are dependent on third parties to manufacture nimacimab.
- We will require substantial additional financing to achieve our goals.
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results.
- Our business may be adversely affected by difficulties or delays in enrolling patients in our current or planned clinical trials or the commencement or completion, or termination or suspension, of our current or planned clinical trials.
- We are dependent on third parties to conduct our pre-clinical and clinical trials.
- Our business activities could be adversely affected by a global pandemic and other epidemic diseases.
- We may not be successful in entering into or maintaining collaborations, licenses and other similar arrangements.
- We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.
- Our results of operations may fluctuate significantly.
- Our business relies on our ability to protect our intellectual property and our proprietary technologies.
- Our executive officers, directors and principal equity holders, if they choose to act together, have the ability to control or significantly influence all matters submitted to stockholders for approval.
- Our stock price is volatile, and investors may incur substantial losses.

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future.

Pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage pharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. To date, we have focused primarily on organizing and staffing our company, business planning, raising capital, discovering potential product candidates, and conducting preclinical studies and clinical trials. Our approach to the discovery and development of product candidates is unproven, and we do not know whether we will be able to develop any products of commercial value. In addition, we have only one product candidate, nimacimab, in clinical development. We have not yet demonstrated an ability to obtain marketing approval for any of our product candidates, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

We have incurred significant operating losses since our inception. If nimacimab is not successfully developed and approved, we may never generate any revenue. We have incurred cumulative net losses since our inception, including a net loss of $55,924,814 and $26,567,123 for the years ended December 31, 2025 and December 31, 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $186,874,486. Our losses have primarily resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. Nimacimab will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as we continue our clinical development of, seek regulatory approval for and potentially commercialize nimacimab. As noted in our consolidated financial statements for the year ended December 31, 2025, the uncertainties surrounding our ability to fund our operations raise substantial doubt about our ability to continue as a going concern.

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern, and if we are unable to continue, you may lose your entire investment.

We have incurred net losses of $55,924,814 and $26,567,123 for the years ended December 31, 2025 and December 31, 2024, respectively, and negative cash flow from operating activities of $43,062,529 and $25,237,480 for same periods. As of December 31, 2025, the Company had $25,737,221 in cash, cash equivalents and short term investments. As a result of our losses and our projected cash needs, combined with our current liquidity level, substantial doubt exists about the Company's ability to continue as a going concern over the next 12 months.

Our historical consolidated financial statements have been prepared under the assumption that we will continue as a going concern. Our independent registered public accounting firm has issued a report on our consolidated financial statements for the year ended December 31, 2025 that included an explanatory paragraph referring to our recurring operating losses and expressing substantial doubt in our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to obtain, among other things, the successful resolution of the Cunning Lawsuit, our ability to obtain additional equity financing or other capital, our ability to implement further operating efficiencies and reduce expenditures, and, ultimately, our ability to successfully commercialize nimacimab and generate revenue, as further described elsewhere in this Annual Report. Our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty, and any such adjustments may be material. Therefore, you should not rely on our consolidated balance sheet as an indication of the amount of proceeds that would be available to satisfy claims of creditors, and potentially be available for distribution to shareholders, in the event of liquidation.

As of December 31, 2025, management estimates that we have sufficient capital to continue our operations through the fourth quarter of 2026, excluding the anticipated clinical cost of a proposed Phase 2b study and additional anticipated drug manufacturing costs to supply any such Phase 2b study. However, our continued operations beyond the fourth quarter of 2026 will depend on our ability to successfully raise additional capital through various potential sources, such as equity and/or debt financings, or strategic relationships. Our ability to access the capital markets is expected to be extremely limited. If we seek additional financing to fund our operations and there remains substantial doubt about our ability to continue as a going concern, our financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all. In addition, the uncertainty as to the resolution of the Cunning Lawsuit could limit our ability to raise new capital from investors to operate our business. If adequate funds are not available to us when needed we will be required to curtail or perhaps cease our operations which would, in turn, further raise substantial doubt about our ability to continue as a going concern.

If we are not successful in improving our liquidity position and the profitability of our operations, we may need to consider all strategic alternatives, including reducing or delaying our business activities and strategic initiatives, selling assets or other strategic transactions and/or other measures, including obtaining relief under the U.S. Bankruptcy Code. In addition, the

perception that we may not be able to continue as a going concern may cause vendors to choose not to do business with us due to concerns about our ability to meet our contractual obligations. If we are unable to continue as a going concern, our stockholders may lose some or all of their investment in us.

We are heavily dependent on the success of nimacimab, which will require significant additional efforts to develop and may prove not to be viable for commercialization.

We have no products approved for sale and nimacimab is our only product candidate in clinical development. Our business depends entirely on the successful development, clinical testing, and commercialization of nimacimab and any other product candidates we may seek to develop in the future, which may never occur.

The success of our product candidates will depend on several factors, any one of which we may not be able to successfully complete, such as:

- our ability to obtain financing to fund the completion of preclinical studies and clinical trials;
- the successful outcome of preclinical studies and clinical trials;
- approval from regulatory agencies, such as the FDA or an IRB, to conduct our clinical trials;
- receipt of marketing approvals from the FDA and other applicable regulatory authorities;
- obtaining, maintaining and protecting our intellectual property portfolio, including patents and trade secrets, and regulatory exclusivity for our product candidates;
- identifying, making arrangements and ensuring necessary registrations with third-party manufacturers, or establishing commercial manufacturing capabilities for applicable product candidates;
- launching commercial sales of the products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement of our products; and
- maintaining a continued acceptable safety profile of our products following approval.

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

We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.

To become and remain profitable, we must succeed in developing, obtaining regulatory approvals for and eventually commercializing or licensing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing clinical trials of nimacimab, discovering additional product candidates, obtaining regulatory approval for nimacimab and any other product candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of only a few of these activities with respect to nimacimab. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. In addition, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do 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 may have an adverse effect on the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidates, achieve our strategic objectives or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.

The development of biopharmaceutical product candidates and conducting preclinical studies and clinical trials is time-consuming and capital-intensive. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our ongoing clinical trial of nimacimab, plan for additional clinical trials and continue our research and development activities. Furthermore, we incur, and expect to continue to incur, additional costs associated with operating as a public company. At the same time, our future commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

The uncertainties surrounding our ability to fund our operations raise substantial doubt about our ability to continue as a going concern. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Furthermore, our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned. Because the outcome of any preclinical study or clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates. Our future capital requirements will depend on many factors, including:

- the type, number, scope, progress, expansions, results, costs and timing of our preclinical studies and clinical trials of nimacimab or any additional product candidates which we are pursuing or may choose to pursue in the future;
- the costs and timing of manufacturing and laboratory testing for nimacimab, including clinical supplies and commercial manufacturing if nimacimab is approved;
- the costs, timing and outcome of regulatory review of nimacimab;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional and retaining existing personnel and consultants as our preclinical and clinical activities increase;
- the costs and timing of establishing or securing sales and marketing capabilities if any product candidate is approved;
- our ability to achieve sufficient market acceptance, adequate coverage and reimbursement from third-party payors and adequate market share and revenue for any approved products;
- the effect of competing technological and market developments;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;
- costs associated with any products or technologies that we may in-license or acquire; and

- the funding of any co-development arrangements we enter into.

Accordingly, we may need to seek additional funds sooner than planned, including through public or private equity or debt financings, other sources, or through strategic collaborations. In May 2024, we entered into an Equity Distribution Agreement with Piper Sandler & Co., as Sales Agent, under which we may sell up to $100.0 million of shares of our common stock through the Sales Agent. However, we have not sold any shares of common stock pursuant to the Equity Distribution Agreement to date and there can be no assurance that the Sales Agent will be successful in consummating future sales based on prevailing market conditions or in the quantities or at the prices that we deem appropriate. In addition, the Equity Distribution Agreement may be terminated by us or the Sales Agent at any time upon ten days' notice to the other party, or by Sales Agent, with respect to itself, at any time in certain circumstances, including the occurrence of a material adverse change. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates. Our ability to raise additional funds may be adversely impacted by global economic conditions, disruptions to, and volatility in, the credit and financial markets in the United States and worldwide, including as a result of volatile interest rates and inflation, and diminished liquidity and credit availability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs, including our clinical trial programs, or any future commercialization of any product candidates, or be unable to sustain or expand our operations or otherwise capitalize on our business opportunities, as desired, any of which could materially affect our business, financial condition and results of operations.

Our ability to raise capital may be limited by applicable laws and regulations.

Using a shelf registration statement on Form S-3 to raise additional capital generally takes less time and is less expensive than other means, such as conducting an offering under a Form S-1 registration statement. However, our ability to raise capital using a shelf registration statement may be limited by, among other things, SEC rules and regulations. We currently have an effective shelf registration on Form S-3 (File No. 333-279331) registering the offering and sale of up to $300,000,000 of our securities. However, under SEC rules and regulations, if our public float (the market value of our common stock held by non-affiliates) is less than $75,000,000, then the aggregate market value of securities sold by us or on our behalf under our Form S-3 in any 12-month period is limited to an aggregate of one-third of our public float. We have been subject to this limitation in the past and we may be subject to it again in the future. If our ability to utilize a Form S-3 registration statement for a primary offering of our securities is limited to one-third of our public float, we may conduct such an offering pursuant to an exemption from registration under the Securities Act or under a Form S-1 registration statement, and we would expect either of those alternatives to increase the cost of raising additional capital relative to utilizing a Form S-3 registration statement.

Our ability to timely raise sufficient additional capital also may be limited by NASDAQ's stockholder approval requirements for transactions involving the issuance of our common stock or securities convertible into our common stock. For instance, NASDAQ requires that we obtain stockholder approval of any transaction involving the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than the greater of book or market value, which (together with sales by our officers, directors and principal stockholders) equals 20% or more of our then outstanding common stock, unless the transaction is considered a "public offering" by NASDAQ. In addition, certain prior sales by us may be aggregated with any offering we may propose in the future, further limiting the amount we could raise in any future offering without stockholder approval. NASDAQ also requires that we obtain stockholder approval if the issuance or potential issuance of additional shares will be considered by NASDAQ to result in a change of control of our company.

Obtaining stockholder approval is a costly and time-consuming process. If we are required to obtain stockholder approval for a potential transaction, we would expect to spend substantial additional money and resources. In addition, seeking stockholder approval would delay our receipt of otherwise available capital or alter the terms of the transaction, which may materially and adversely affect our ability to execute our business strategy, and there is no guarantee our stockholders ultimately would approve a proposed transaction.

Public opinion and scrutiny of treatments for obesity and overweight may impact public perception of us or nimacimab, or may adversely affect our ability to conduct our business and our business plans.

Public perception of our business may be influenced by claims, such as claims that nimacimab is unsafe, unethical or immoral and, consequently, our approach may not gain the acceptance of the public or the medical community. Negative public reaction to treatments for obesity and overweight in general could result in greater government regulation and stricter labeling requirements of products to treat these chronic conditions, including nimacimab, if approved, and could cause a decrease in the demand for nimacimab or any other product candidates we may develop. Adverse public attitudes may also adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians specializing in the treatment of those diseases that nimacimab targets, and their patients being willing to receive, treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. Adverse events in our clinical trials, even if not ultimately attributable to our product candidate, and the resulting publicity could result in withdrawal of clinical trial participants, increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates. More restrictive government regulations or negative public opinion could have an adverse effect on our business, financial condition, results of operations and prospects, and may delay or impair the development and, if approved, commercialization of nimacimab or demand for any additional products we may develop.

Risks Related to Product Development, Regulatory Approval, Manufacturing and Commercialization

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

Because we have limited financial resources and we have limited employee bandwidth which could minimize the indications we pursue, we have historically focused our development efforts on certain selected product candidates in certain selected indications. For example, while we previously focused on nimacimab as a monotherapy, we are currently focused on the development of nimacimab in combinations with a GLP-1 receptor agonist, for obesity and overweight. As a result, we may forgo or delay pursuit of opportunities with other product candidates, or other indications for our existing product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future development programs and product candidates for specific indications may not yield any commercially viable product candidates. At any time, we may decide to discontinue the development or commercialization of nimacimab or any additional products or product candidates for a variety of reasons, including the appearance of new technologies that render our products obsolete, competition from a competing product, or changes in or inability to comply with applicable regulatory requirements. For example, in 2024 we determined to eliminate our prior ocular program and strategically redirected our efforts and capital resources to nimacimab. If we terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have missed the opportunity to allocate those resources to potentially more productive uses. In addition, 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.

Nonclinical and clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. The results of prior clinical studies and preclinical studies are not necessarily predictive of future results, and may not be favorable, or receive regulatory approval on a timely basis, if at all.

Clinical drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the preclinical or clinical trial process. The historical failure rate for product candidates in our industry is high.

The results from preclinical studies or clinical trials of nimacimab or a competitor's product candidate in the same class may not predict the results of later clinical trials of nimacimab, and interim, top-line or preliminary results of a clinical trial are not necessarily indicative of final results. It is possible to observe results in clinical trials that are unexpected based on preclinical studies, such as DIO studies and early clinical trials, and many product candidates fail in clinical trials despite very promising early results. For example, the Phase 2a nimacimab results and the length of the study and sample size may render these results not necessarily indicative of the results of our future clinical studies for nimacimab and may not be comparable to other weight loss products or product candidates. Product candidates in later stages of clinical studies may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical studies. In particular, while we have conducted, or are conducting certain preclinical studies of our product candidates, the predictive value of these studies with respect to future testing in humans is limited, particularly in indications where animal models are less developed.

If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of nimacimab, if we do not meet our clinical endpoints with statistical significance or if there are safety concerns or adverse events associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for our product candidates, or we may suspend or delay development of or abandon specific product candidates. For example, we suspended the development of our prior product candidate, SBI-100 Opthalmic Emulsion ("SBI-100 OE") when the Phase 2a clinical trial in patients with primary open-angle glaucoma or ocular hypertension did not meet its primary endpoint for lowering intraocular pressure. In addition, in October 2025, we announced the results from our CBeyond Phase 2a proof-of-concept clinical trial of nimacimab administered as a subcutaneous injectable for the treatment of obesity and overweight in the United States. The nimacimab monotherapy arm did not achieve the primary endpoint of weight loss compared to placebo. As a result, we are currently focused on the development of nimacimab in combinations with a GLP-1 receptor agonist, for obesity and overweight.

For the foregoing reasons, we cannot be certain that our ongoing and planned clinical trials and preclinical studies of nimacimab will be successful. Any safety concerns observed in any one of our clinical trials could limit the prospects for regulatory approval of nimacimab in obesity and other indications, which could have a material adverse effect on our business.

Any difficulties or delays in the commencement or completion, or termination or suspension, of our current or planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. In addition, before we can initiate clinical development for our product candidates, and in some cases, before we can pursue clinical development of a product candidate for a new potential indication, we must submit the results of preclinical studies to the FDA along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND, and we are also required to submit regulatory filings to foreign regulatory authorities for clinical trials outside of the United States. We do not know whether our planned trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons including delays related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies;
- regulators or IRBs may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites or CROs the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- regulators or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- changes to clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- manufacturing sufficient quantities of nimacimab or obtaining sufficient quantities of combination therapies, such as semaglutide, for use in clinical trials;
- subjects enrolling or failing to enroll or remain in our trials at the rate we expect, or failing to return for post-treatment follow-up, including subjects failing to remain in our trials;
- subjects choosing an alternative treatment for obesity or other indications for which we may be developing nimacimab for, or participating in competing clinical trials;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- facility manufacturing nimacimab or any of its components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of cGMP or similar foreign regulations or other applicable requirements;
- any changes to our manufacturing process that may necessary or desired;

- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, GCP, or other regulatory requirements; third-party contractors not performing data collection or analysis in a timely or accurate manner;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications; or
- nimacimab may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs to suspend or terminate the clinical trials.

Such delays or regulatory feedback on our trial designs could also significantly increase the costs of our clinical trials. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs or ethics committees for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

If we experience delays or difficulties in the enrollment or retention of patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may not be able to initiate or continue clinical trials for nimacimab if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In addition, there are many companies that have products that treat, or have ongoing clinical trials for product candidates for the treatment of, obesity and overweight, and patients who would otherwise be eligible for our clinical trials may instead forgo participating in a clinical trial due to the availability of an approved treatment or may enroll in clinical trials of a competitors' product candidate. Patient enrollment is affected by a number of factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the risk that enrolled patients will not complete a clinical trial, our ability to recruit clinical trial investigators and associated staff with the appropriate competencies and experience, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks 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 as well as any drugs under development.

Additionally, patients, including patients in a control group, may withdraw from or otherwise discontinue our clinical trials if they do not experience weight loss or changes in body composition at their desired rate, experience side effects, experience other difficulties or issues, do not comply (or do not wish to continue complying with) study protocol, or for other reasons. Withdrawals and other patient discontinuations may compromise the quality of our data and may cause or contribute to a trial's failure to demonstrate proof-of-concept or meet its clinical endpoints with statistical significance, or may result in skewed safety results or adverse events associated with our product candidate. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in enrollment or retention issues may result in increased costs or may affect the timing or outcome of our clinical trials. Any of these conditions may negatively impact our ability to complete such trials or include results from such trials in regulatory submissions, which could adversely affect our product development efforts.

The timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as patient retention and completion of required follow-up periods. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will have limited influence over their actual performance.

We cannot assure you that our assumptions used in determining expected clinical trial timelines are correct or that we will not experience delays in enrollment or patient retention issues, which could negatively impact our product development efforts.

Serious adverse events or undesirable side effects or other unexpected properties of nimacimab may be identified during development or after approval that could delay, prevent or cause the withdrawal of marketing approval, limit the commercial potential, or result in significant negative consequences following marketing approval.

Serious adverse events or undesirable side effects caused by, or other unexpected properties of, nimacimab could cause us, an IRB, or regulatory authorities to interrupt, delay or halt our clinical trials and could result in a more restrictive label, the imposition of distribution or use restrictions or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. If nimacimab is associated with serious adverse events or undesirable side effects or have properties that are unexpected, we may need to abandon its development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In our completed Phase 2a study of nimacimab, the 200 mg dose of nimacimab demonstrated a favorable safety profile, with no increases in neuropsychiatric adverse events reported resulting from the treatment with nimacimab. However, further analysis and clinical data from doses above the 200 mg dose used in the Phase 2a study may reveal adverse events inconsistent with the safety results previously observed. Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause undesirable or unexpected side effects that prevented further development of the compound. For example, in 2006, Sanofi developed a small molecule CB1 inverse agonist called rimonabant which demonstrated 10% weight loss after one year. Despite being approved by the European Medicines Agency, the drug was soon taken off the market due to severe adverse neuropsychiatric side effects, including suicidal ideation.

Undesirable side effects or other unexpected adverse events or properties of nimacimab or any of our future product candidates could arise or become known either during clinical development or, if approved, after the approved product has been marketed. If such an event occurs during development, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of, or deny approval of, our product candidates. If such an event occurs after such product candidates are approved, a number of potentially significant negative consequences may result, including withdrawal of regulatory approval, requirements for additional warnings on the label, use or distribution restrictions, requirements to conduct post-market studies, requirements to create a medication guide outlining side effects, and liability for harm caused to patients.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved, or could substantially increase commercialization costs and expenses, which could delay or prevent us from generating revenue from the sale of our products and harm our business and results of operations.

As an organization, we have never conducted later-stage clinical trials or submitted an NDA or BLA, and may be unable to do so for any of our product candidates.

We are early in our development efforts for nimacimab, and we will need to successfully complete pivotal clinical trials in order to seek FDA or applicable foreign authority approval to market nimacimab and any future product candidates we may develop. Carrying out clinical trials and the submission of NDAs and BLAs are complicated. Based on the stage of development of nimacimab, the Company has not conducted any later stage or pivotal clinical trials. This may be a difficult process to manage with our limited resources and may divert the attention of management. In addition, we cannot be certain how many clinical trials of our product candidates will be required or how such trials will have to be designed to obtain marketing authorization. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to regulatory submission and approval of any of our product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining marketing approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in submitting NDAs for and commercializing our product candidates.

Nimacimab is subject to extensive regulation and compliance, which is costly and time consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required approvals to commercialize nimacimab.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of nimacimab is subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in foreign markets. In the United States, we are not permitted to market nimacimab in foreign jurisdictions until we receive regulatory approval from the FDA and similarly, we are not permitted to market nimacimab until we receive foreign regulatory authorities' approval. The process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and the FDA and foreign regulatory authorities have substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

Prior to obtaining approval to commercialize nimacimab in the United States or abroad, we must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that nimacimab is safe and effective for its intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for nimacimab is promising, such data may not be sufficient to support approval by the FDA and comparable foreign regulatory authorities, which could require us to delay or abandon clinical development plans. Further, requirements regarding clinical trial data may evolve. For example, the FDA published a draft guidance, E6 (R3) Good Clinical Practice, in June 2023, and Annex 2 thereto in December 2024, which seeks to unify standards for clinical trial data for ICH member countries and regions. Changes to data requirements by the FDA or comparable foreign regulatory authorities, as the case may be, may cause the applicable regulatory authorities to also require us to conduct additional preclinical studies or clinical trials for nimacimab either prior to or post-approval, or may object to elements of our clinical development program.

The FDA or comparable foreign regulatory authorities could delay, limit or deny approval of nimacimab for many reasons, including:

- such authorities may disagree with the design or implementation of our clinical trials;
- negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval;
- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to nimacimab;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- we may be unable to demonstrate that nimacimab's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- such authorities may not agree that the data collected from clinical trials of nimacimab are acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials
- such authorities may disagree regarding the formulation, labeling and/or the specifications of nimacimab;
- approval may be granted only for indications that are significantly more limited than what we apply for and/or with other significant restrictions on distribution and use;
- such authorities may find deficiencies in the manufacturing processes or facilities of our third-party manufacturers with which we contract for clinical and commercial supplies; or the approval policies;
- regulations of such authorities may significantly change in a manner rendering our or any of our potential future collaborators' clinical data insufficient for approval;
- such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission; or
- the FDA or other comparable foreign regulatory authorities may experience disruptions to the review or approval process.

With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new drugs based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us or any of our potential future collaborators from commercializing nimacimab.

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

Even if we eventually complete clinical trials and receive approval of an NDA or BLA or foreign marketing application for nimacimab, the FDA or comparable foreign regulatory authority may grant approval contingent on the performance of costly

additional clinical trials, including Phase 4 clinical trials, and/or the implementation of a REMS or similar risk management measures, which may be required to ensure safe use of the drug after approval. The FDA or the comparable foreign regulatory authority also may approve nimacimab for a more limited indication or patient population than we originally requested, and the FDA or comparable foreign regulatory authority may not approve the labeling that we believe is necessary or desirable for the successful commercialization of a product. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of nimacimab and would materially adversely impact our business and prospects.

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. We also 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. For example, the prior presidential administrations have taken several executive actions that imposed significant burdens on, or otherwise materially delayed, the FDA's ability to engage in routine oversight activities, such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict whether or how any current executive orders will be rescinded and replaced under the current administration. The policies and priorities of any administration and the U.S. Congress are unknown and could materially impact the regulations governing our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or they are not able to maintain regulatory compliance, we or they may be subject to enforcement action, and we may not achieve or sustain profitability.

We have conducted clinical trials for our product candidates outside of the United States and we may do so for our product candidates in the future. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We have conducted our initial certain portions of the Phase 1 clinical trial nimacimab in Australia and we may in the future conduct, one or more of our clinical trials for nimacimab outside the United States. The acceptance of study data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or a comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. For example, in cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; 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 adequately designed and well-controlled, conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. If the FDA or other foreign equivalents do not accept any data generated from other jurisdictions, we would likely be required to conduct additional clinical trials, which would be costly and time consuming, and delay aspects of our development plan, which could harm our business.

Conducting trials outside the United States also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research;
- diminished protection of intellectual property in some countries; and
- interruptions or delays in our trials resulting from geopolitical events, such as war or terrorism.

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

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses. Others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

The manufacture and maintenance of our clinical product candidate is complex and we may encounter difficulties in production and maintenance, particularly with respect to clinical material inventory, acquisition of materials, process development or scaling-up of our manufacturing capabilities.

The manufacture and maintenance of our biologic product candidate, nimacimab, is complex, highly regulated and subject to multiple risks. The complex processes associated with the manufacture of nimacimab exposes us to various manufacturing challenges and risks, which may include delays in manufacturing nimacimab, limits on our ability to increase manufacturing capacity, and the potential for product failure and product variation that may interfere with the timing and scope of our clinical development plans and add additional costs. It is possible that we will make changes to our manufacturing process for nimacimab at various points during product development or commercialization for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate, or other reasons. Such changes can be costly and carry the risk that they will not achieve their intended objectives, or these changes could cause nimacimab to perform differently and affect the results of current or future clinical trials, or the performance of a commercialized product. In some circumstances, changes in the manufacturing process may require us to perform analytical or clinical comparability studies and to collect additional data prior to undertaking more advanced clinical trials, and such studies may introduce additional costs or delays to the program. We may be required to collect additional clinical data from any modified process prior to obtaining marketing approval for the product candidate produced with such modified process. If clinical data are not ultimately comparable to that seen in the earlier trials in terms of safety or efficacy, we may be required to make further changes to our process and/or undertake additional clinical testing, either of which could significantly delay the clinical development or commercialization of the associated product candidate.

Compliance with cGMP requirements and other quality or regulatory issues may arise with our current or any future contract manufacturing organizations (“CMOs”). Furthermore, ongoing stability studies subsequent to manufacture must be periodically conducted to demonstrate that each of our product candidates do not undergo unacceptable deterioration over its shelf life. If issues affecting the quality of our product candidates or those of our CMOs are discovered, the timing and scope of our clinical trials may be delayed or modified and in certain instances such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the issue. To the extent any adversely affected material is being used in an ongoing clinical trial, such as our CBeyond clinical trial, the FDA could impose a clinical hold on our trial to investigate and remedy the quality issue. We cannot assure that any manufactured product or product candidate will not suffer a loss in stability or that other issues relating to the manufacture of our product candidates will not occur in the future.

Additionally, our CMOs may experience manufacturing difficulties due to resource constraints, including manufacturing capacity, material constraints, or as a result of labor disputes or unstable political environments. If our CMOs were to encounter any of these difficulties, our ability to provide our product candidate to patients in clinical trials, or to provide product for treatment of patients once approved, would be jeopardized.

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

The ability of the FDA and other government agencies to review and approve new products can be affected by a variety of factors, including government budget and funding levels, staffing cuts, the FDA's ability to hire and retain key personnel and accept the payment of user fees, statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA's' ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. The ability of the FDA and other government agencies to properly administer their functions is highly dependent on the levels of government funding and the ability to fill key leadership appointments, among various factors. Delays in filling or replacing key positions could significantly impact the ability of the FDA and other agencies to fulfill their functions and could greatly impact healthcare and the drug industry. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and biologics or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government shut down several times and certain regulatory agencies, such as the FDA, furloughed critical employees and ceased critical activities. In the event of a partial or complete government shutdown, the FDA and certain other scientific agencies may temporarily cease certain operations. Furthermore, during such shutdown, the FDA may maintain only operations deemed to be essential for public health while suspending the acceptance of new medical product applications and routine regulatory and compliance work related to medical products, certain drugs, and foods. Disruptions at the FDA and other agencies, such as those resulting from a restructuring of these agencies, a prolonged government shutdown, or uncertainty regarding U.S. federal government funding, could significantly affect the ability of the FDA to review and process our regulatory submissions in a timely manner, which could have a material adverse effect on our business.

Government funding of research and development is subject to the political and budgetary process, which is inherently uncertain. Changes in federal funding priorities or reductions in funding from agencies such as the National Institutes of Health ("NIH") could adversely affect research programs related to our products and studies. In addition, proposals have periodically been made to reduce reimbursement of indirect costs associated with federally funded research. While certain such proposals have been challenged or blocked, there can be no assurance that similar policies will not be adopted in the future, which could adversely affect our business and financial results.

Further, in June 2024, the U.S. Supreme Court reversed its longstanding approach under the Chevron doctrine, which provided for judicial deference to regulatory agencies, including the FDA. As a result of this decision, we cannot be sure whether there will be increased challenges to existing agency regulations or how lower courts will apply the decision in the context of other regulatory schemes without more specific guidance from the U.S. Supreme Court. For example, this decision may result in more companies bringing lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, which could impact the timely review of any regulatory filings or applications we submit to the FDA.

Additional time may be required to obtain marketing authorizations for any product candidates that we develop as biologic-device combination products.

We expect our current injectable product candidate, nimacimab, will be regulated as a combination product, as our therapeutic candidates will be administered by the patient using a disposable injector device marketed together with the therapeutic candidate, if approved, and in at least one case, we anticipate combining a drug and biologic candidate together for administration using a device. Development of a product candidate as a combination product candidate requires close coordination within the FDA and within comparable regulatory agencies for review of each of the drug, biologic, and device components that comprise the product and would typically be reviewed by different centers within the FDA if offered for use as standalone products. For example, the FDA's review of a marketing application for a biologic-device combination that has a primary mode of action as a biologic would likely be subject to a biologics license application with the Center for Biologics Evaluation and Research as the lead center, with coordination with the Center for Devices and Radiological Health for the review of the device component. Although the FDA and comparable foreign agencies have or may have systems in place for the review and approval of such combination products, we may experience additional delays in the development and

commercialization of such product candidates due to regulatory timing constraints and uncertainties in the product development and approval process. Moreover, although we anticipate that the device component of any combination product candidates we develop will be reviewed within the usual time frames expected for the marketing authorization application for underlying therapeutic candidate, and that no separate marketing application for the device components of such product candidates will be required in the United States, the FDA or comparable regulatory authorities may delay approval or require us to conduct additional studies with the device, which may delay the approval of the combination product.

Separately, to the extent we seek approval for use of any of our product candidates in combination with GLP-1 receptor agonists, FDA may require us to conduct additional studies to evaluate the safety and efficacy of the combination regimen, including to address potential additive or overlapping adverse events, dosing considerations, and patient selection. If we seek labeling that references use with a specific third-party GLP-1 product, we may be unable to obtain or maintain such labeling without cooperation from the applicable third party and/or changes to that third party's labeling, which is outside of our control.

Risks Related to Our Reliance on Third Parties

We expect to continue to rely on third parties, such as CROs, to conduct some or all of our preclinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize any of our product candidates.

We expect to continue to rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct our preclinical and clinical studies on our product candidates in compliance with applicable regulatory requirements. For example, we are currently engaged with a CRO in the United States, to conduct our Phase 2 clinical study for nimacimab. These third parties will not be our employees and, except for restrictions imposed by our contracts with such third parties, we will have limited ability to control the amount or timing of resources that they devote to our programs. Although we expect to rely on these third parties to conduct our preclinical studies and clinical trials, we will remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and the applicable legal, regulatory, and scientific standards, and our reliance on these third parties will not relieve us of our regulatory responsibilities. The FDA and comparable foreign regulatory authorities in other jurisdictions require us to comply with regulations and standards, commonly referred to as current good clinical practices, for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. If we or any of our third party contractors fail to comply with applicable current good clinical practices, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, we are required to report certain financial interests of our third party investigators if these relationships exceed certain financial thresholds and meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by principal investigators who previously served or currently serve as scientific advisors or consultants to us from time to time and receive cash compensation in connection with such services. Our clinical trials must also generally be conducted with products produced under current good manufacturing practice regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

There is no guarantee that any such CROs, investigators or other third parties will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise performs in a substandard manner, our clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom we may contract may also have relationships with other commercial entities, some of which may compete with us. If the third parties conducting our preclinical studies or our clinical trials do not perform their contractual duties or obligations or comply with regulatory requirements, we may need to enter into new arrangements with alternative third parties. This could be costly, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated, and we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable product candidate, or to commercialize such product candidate being tested in such studies or trials. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third party contractors or to do so on commercially reasonable terms. Though we plan to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely on, and expect to continue relying on, third party contract manufacturing organizations to manufacture and supply nimacimab for us. This reliance on third parties increases the risk that we will not have sufficient quantities of nimacimab or such quantities at an acceptable cost, which could delay or impair our development efforts.

We do not own facilities for, manufacturing our product candidates and have no plans to build our own clinical or commercial scale manufacturing capabilities. We rely on, and expect to continue relying upon, third party manufacturing organizations to manufacture and supply nimacimab and certain raw materials used in the production thereof.

The facilities used by our contract manufacturers to manufacture nimacimab must be approved by the FDA pursuant to inspections that will be conducted after we submit our BLA to the FDA or similar applications to foreign regulatory authorities. We expect that we will not control the manufacturing process of, and will be completely dependent on, our contract manufacturing partners for compliance with current good manufacturing practice requirements, for manufacture of our drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we expect that we will have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of nimacimab or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our nimacimab, if approved.

Our or a third party's failure to execute on our manufacturing requirements, to do so on commercially reasonable terms and comply with cGMP or similar requirements outside of the United States could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of nimacimab, or any future product candidates under development as well as subsequent clinical studies of nimacimab;
- delay in submitting regulatory applications, or receiving marketing approvals, for nimacimab;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of nimacimab; and
- in the event of approval to market and commercialize nimacimab, an inability to meet commercial demands for nimacimab.

In addition, we do not have long-term commitments or supply agreements with all of our third-party manufacturers. We may be unable to establish any supply agreements with third-party manufacturers or to do so on acceptable terms, which increases the risk of timely obtaining sufficient quantities of nimacimab or such quantities at an acceptable cost. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third party;
- failure to manufacture nimacimab according to our specifications;
- failure to manufacture nimacimab according to our schedule or at all;
- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Nimacimab and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP or similar foreign regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time consuming to implement. We do not currently have arrangements in place for redundant supply or a second source for all required raw materials used in the manufacture of nimacimab. Further, our third-party manufacturers may experience manufacturing or shipping difficulties due to resource constraints or as a result of natural disasters, labor disputes, unstable political environments, or public health epidemics. If our current third-party manufacturers cannot perform as agreed, we may be required to replace such manufacturers, and we may be unable to replace them on a timely basis or at all.

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

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 currently rely on other third parties in the discovery, development, and manufacture of our product candidates, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into non-disclosure and confidentiality agreements, consulting agreements or other similar agreements with our advisors, employees, consultants, contractors, investigators, advisors, collaborators, manufacturers, suppliers, and other third parties prior to disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. For example, these agreements typically restrict the ability of the third parties to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with in the future may be granted rights to publish data arising out of such collaboration, subject to certain notice and publication delay requirements in order for us to secure patent protection of intellectual property rights arising from the collaboration, in addition to the opportunity to remove confidential or trade secret information from any such publication. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are intentionally or 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 and despite our efforts to protect our proprietary information, a competitor's discovery of our proprietary technology and confidential information or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

If we fail to enter and maintain successful collaborative arrangements or strategic alliances for our product candidates, we may have to reduce or delay our product candidate development or increase our expenditures.

An important element of our strategy for developing, manufacturing and commercializing our product candidates is entering into collaborative arrangements or strategic alliances with pharmaceutical companies, research institutions or other industry participants to advance our programs and enable us to maintain our financial and operational capacity. We may not be able to negotiate alliances on acceptable terms, if at all. In addition, these alliances may be unsuccessful. If we fail to create and maintain suitable alliances, we may have to limit the size or scope of, or delay, one or more of our research or development programs.

In addition, these kinds of collaborative arrangements and strategic alliances may place certain aspects of the development of our product candidates outside of our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

Dependence on collaborative arrangements or strategic alliances will subject us to several risks, including the risks that:

- we may not be able to control the amount and timing of resources that our collaborators may devote to the product candidates;
- a significant change in the senior management team, a change in the financial condition or a change in the business operations, including a change in control or internal corporate restructuring, of any of our collaborators, could result in delayed timelines, re-prioritization of our programs, decreasing resources or funding allocated to support our programs, or termination of the collaborations;
- we may be required to relinquish important rights such as marketing and distribution rights;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- a collaborator could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors;
- collaborative arrangements are often terminated or allowed to expire, which would delay development and may increase the cost of developing our product candidates;
- collaborators may not comply with all applicable regulatory and legal requirements

Risks Related to Commercialization

Even if we receive marketing approval for a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to restrictions, withdrawal from the market, or penalties if we fail to comply with applicable regulatory requirements or if we experience unanticipated problems with our product candidates, when and if approved.

Following potential approval of nimacimab or any of our future product candidates, the FDA or comparable foreign regulatory authorities may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly and time-consuming post-approval studies, post-market surveillance or clinical trials to monitor the safety and efficacy of the product. For example, the FDA may also require the implementation of a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCP requirements for any clinical trials that we conduct post-approval.

In addition, the FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off label uses, we may become subject to significant liability. 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 sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Furthermore, later discovery of previously unknown problems with our products, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA or comparable foreign regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our products; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay commercialization of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action, as a result of which we may not achieve or sustain profitability, which would have a material adverse effect on our business, reputation, prospectus and financial condition.

We face significant competition from entities that have made substantial investments into developing novel treatment for patients with obesity and overweight, including large pharmaceutical companies with approved therapies in our current indications, and biopharmaceutical, specialty pharmaceutical and biotechnology companies developing novel treatments and technology platforms. If the companies develop competing technologies or product candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize products may be adversely affected.

The development and commercialization of therapies for the treatment of obesity and overweight is highly competitive. Our product candidate, nimacimab, if approved, will face significant competition, including from well-established, currently marketed therapies that have been developed by large, well-known pharmaceutical companies, and our failure to demonstrate a meaningful improvement to the existing standard of care may prevent us from achieving significant market penetration. In particular, there is intense competition in the obesity and overweight field, especially with the advent of GLP-1 RAs, such as Wegovy, marketed by Novo Nordisk, and Zepbound, marketed by Eli Lilly. In addition to injectable therapies for overweight and obesity, Wegovy became the first FDA approved oral GLP-1 receptor agonist in December 2025 and other oral therapies are in development for treating overweight and obesity, including those being development by Eli Lilly, Structure Therapeutics, and Viking Therapeutics. There are numerous other companies that have commercialized or are developing treatments for obesity and overweight that we will compete with, including those entities listed in the section entitled "Competition" in Item 1 of this Annual Report. Competitors to nimacimab that are targeting peripheral inhibition of CB1 for the treatment of obesity and metabolic conditions include Novo Nordisk and their development effort of monlunabant. We face competition from these companies and other major pharmaceutical and biotechnology companies, including specialty pharmaceutical companies, academic institutions, governmental agencies and public and private research institutions, among others.

Many of these aforementioned products have been marketed for several years and are well established among physicians, patients, guidelines and third-party payers, creating potential adoption challenges for new entrants, such as requiring demonstration of incremental value or benefits and/or reduction of healthcare system costs. These challenges will impact current and future products as they look to enter or expand the market.

We anticipate that we will continue to face increasing competition as new therapies and combinations thereof, and related data, emerge. Competitors, independently or through collaboration, are developing products that potentially directly compete with our current of future product candidates and which may be a longer lasting or a more efficacious treatment, or receive FDA or other applicable regulatory approval more rapidly than any of our current or future product candidates. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient (such as oral therapies) or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other applicable regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. There are generic products currently on the market for certain of the indications that we are pursuing and additional products are expected to become available on a generic basis over the coming years. If our product candidates are approved, we expect that they will be priced at a significant premium over competitive generic products.

Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do.

Moreover, many of these aforementioned competing products have been marketed for several years and are well established among physicians, patients and guidelines. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified management and other personnel and establishing clinical trial sites and participants registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for our programs.

Any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") established an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for

the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency (or efficacy) of its product.

We believe that nimacimab, if approved as a biological product under a BLA should qualify for the 12-year period of reference product exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that continue to develop.

Even if nimacimab or our future product candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

Even if nimacimab or our future product candidates receive marketing approval, they may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If they do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of nimacimab or our future product candidates, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the clinical indications for which the product candidate is approved;
- the efficacy and potential advantages compared to alternative treatments and therapies;
- the timing of market introduction of the product as well as competitive products;
- effectiveness of sales and marketing efforts;
- the strength of our relationships with patient communities;
- the cost of treatment in relation to alternative treatments and therapies, including any similar generic treatments;
- our ability to offer such product for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments and therapies;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the availability of third-party coverage and adequate reimbursement;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors and government authorities;
- the strength of marketing and distribution support;
- the prevalence and severity of any side effects; and
- any restrictions on the use of the product together with other medications.

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our product candidates may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our product candidates. Because we expect sales of our product candidates, if approved, to generate substantially all of our revenues for the foreseeable future, the failure of our product candidates, if approved, to find market acceptance would harm our business and could require us to seek additional financing.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found or alleged to have improperly promoted off-label uses, we may become subject to significant liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, as nimacimab would be, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of nimacimab, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

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

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as nimacimab, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize those products. Even if 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 United States, the European Union 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 or a less expensive therapy is available. It is possible that a third-party payor may consider our products as substitutable and only offer to reimburse patients for the less expensive product. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with our products, pricing of existing drugs may limit the amount we will be able to charge for our products. 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 products 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 United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse health care 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 products.

Obtaining and maintaining reimbursement status is time-consuming, costly and uncertain. 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. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. 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.

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

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products. For example, in May 2025, the current administration published an executive order that expressed support for equalizing the prices paid for drugs in the United States and other developed countries by employing a most favored nation, or MFN, approach to drug pricing and in September and October 2025, CMS submitted proposed rules for Center for Medicare and Medicaid Innovation (CMMI) models, called the Global Benchmark for Efficient Drug Pricing (GLOBE) Model and Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model, to the White House for review. These models, if implemented, may allow CMS to pursue formalized approaches to MFN pricing for prescription drugs. In addition, in November 2025, CMS published a request for applications for another CMMI model, the GENEROUS (GENErating cost Reductions for U.S. Medicaid) Model. This is a voluntary model that tests the effect of supplemental rebate agreements between manufacturers and CMS, which align Medicaid prices with a defined MFN price. The scope of these models and the impact that they could have on any of our products is unclear at this time.

We expect to experience pricing pressures in connection with the sale of any of our products 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 and surgical procedures and other treatments, has become very intense. In addition, communications from government officials, media outlets, and others regarding health care costs and pharmaceutical pricing could have a negative impact on our stock price, even if such communications do not ultimately impact coverage or reimbursement decisions for our products. Further, we are unable to predict which or how many policy, regulatory, administrative or legislative changes may ultimately be, or effectively estimate the consequences to our business if, enacted and implemented. However, to the extent that payer actions further decrease or modify the coverage or reimbursement available for our products, require that we pay increased rebates or shift other costs to us, limit or affect our decisions regarding the pricing of or otherwise reduce the use of our products, such actions could have a material adverse effect on our business and results of operations.

If the market opportunities for any of our product candidates are smaller than we estimate, even assuming approval of a product candidate, our future revenue may be adversely affected, and our business may suffer.

The precise incidence and prevalence for all the conditions we aim to address with nimacimab are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with nimacimab, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new information may change the estimated incidence or prevalence of these diseases. The total addressable market nimacimab will ultimately depend upon, among other things, the diagnosis criteria included in the final label for nimacimab approved for sale for these indications, the availability of alternative treatments and the safety, convenience, cost and efficacy of our product candidates relative to such alternative treatments, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with nimacimab or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue.

We have no internal sales, marketing or distribution capabilities, nor have we as a company commercialized a product. If any nimacimab ultimately receives marketing approval, we will be required to build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize nimacimab in the markets that we target, which will be expensive and time consuming, or collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We have no prior experience as a company in the marketing, sale and distribution of biopharmaceutical products and there are significant risks and costs involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training (e.g., about our products and compliance with applicable laws) to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities or implementation of adequate controls and monitoring to ensure that our sales and marketing activities are in compliance with applicable laws would adversely impact the commercialization of these products. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively or in compliance with applicable laws. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

Our future growth may depend, in part, on our ability to commercialize products in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for any of our product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution of our product candidates. If we obtain regulatory approval of our product candidates and ultimately commercialize our products in foreign markets, we would be subject to additional risks and uncertainties, including:

- different regulatory requirements for approval of drugs in foreign countries;
- reduced protection for intellectual property rights;
- the existence of additional third-party patent rights of potential relevance to our business;
- unexpected changes in tariffs, trade barriers, regulatory requirements;
- economic weakness, including inflation, or political instability in particular domestic and foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is common;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

Risks Related to Our Business Operations and Industry

Our ability to become profitable and continue as a going concern will be dependent on our ability to attract, employ and retain highly qualified personnel.

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends in part on upon our continued ability to attract, recruit, retain, manage and motivate highly qualified managerial, scientific and medical personnel. We are highly dependent upon our senior management, as well as our senior scientists and other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our planned clinical trials or the commercialization of nimacimab. For example, in the first quarter of 2026, we experienced the departure of certain key personnel and are supplementing any required resources for our business operations with subject-matter-expert (SME) contractors. This loss of expertise and background knowledge may create challenges in maintaining operational continuity, meeting regulatory and financial reporting requirements, and supporting our strategic objectives. Replacing these personnel with qualified individuals may be difficult and could require additional and unanticipated costs and challenges including costs associated with engaging additional financial advisors and the challenges of bringing such third-party advisors current on our operations.

Although we have executed employment agreements with each member of our senior management team, these agreements are terminable at will with or without notice, and therefore, we may not be able to retain their services as expected. We do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

In addition, the competition for qualified personnel in the pharmaceutical industry is intense and there can be no assurance that we will be able to continue to attract and retain all personnel necessary for the development and operation of our business. There is no guarantee that skilled persons will be available and willing to work for us in the future, nor is there any guarantee that we could afford to retain them if they are available at a future time. We also rely on, and have relied on in the past, consultants and advisors to assist us in formulating our strategy. Our consultants and advisors are either self-employed or employed by other organizations, and they may have conflicts of interest or other commitments, such as consulting or advisory contracts with other organizations, that may affect their ability to contribute to us.

In addition, employment candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, either because we are a public company or for other reasons, it may harm our ability to recruit and retain highly skilled employees. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock.

Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future marketing approvals, sales of our product candidates and our results of operations.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As of March 9, 2026, we had 12 full-time employees. In the first quarter of 2026, we reduced our workforce in order to reduce operating costs. However, as we continue development and pursue the potential commercialization of our product candidates, as well as function as a public company, we will need to expand our financial, development, regulatory, manufacturing, operational, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to develop and commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively, which would have a material adverse effect on our business.

We are subject to various foreign, federal and state healthcare laws and regulations, and our failure to comply with these laws and regulations could harm our results of operations and financial condition.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors and customers expose us to broadly applicable federal and state fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any products for which we obtain marketing approval. Such laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain

rebates), directly or indirectly, overtly or covertly, in cash or in kind, in return for, either the referral of an individual or the purchase, lease, or order, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal statute or specific intent to violate it in order to have committed a violation;

- the federal false claims, including the civil False Claims Act, which, among other things, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the 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 or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- 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 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.
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments and other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, anesthesiology assistants and certified nurse midwives), and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members; and
- analogous state and foreign laws and regulations, such as 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 non- governmental third-party payors, including private insurers, or by the patients themselves; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the 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 physicians, other healthcare providers and entities; state and local laws that require the registration of pharmaceutical sales representatives.

Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our consulting and advisory board arrangements with physicians and other healthcare providers, some of whom receive stock options as compensation for services provided, 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, individual imprisonment, contractual damages, reputational harm, 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, diminished profits and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly, 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 are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusion 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.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could have a material adverse effect on our business, financial condition or results of operations.

Privacy and data security have become a significant area of focus in the U.S., and in many other jurisdictions where we may in the future conduct our operations. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues, which may affect our business and may increase our compliance costs and exposure to liability. As we receive, collect, process, use and store personal and confidential data, we are or may be subject to multiple laws and regulations relating to data privacy and security. Compliance with these privacy and data security requirements is rigorous and time-intensive and may increase our cost of doing business, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm, which could materially and adversely affect our business, financial condition and operations.

In the U.S., we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA imposes, among other things, requirements relating to the privacy, security, transmission and breach reporting of PHI held by covered entities and their business associates. We may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

In addition, state laws govern the privacy and security of health-related and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same requirements, thus complicating compliance efforts. Several states, including California, Colorado, Connecticut, Utah and Virginia, have adopted generally applicable and comprehensive privacy laws, although most have an exception for information regulated by HIPAA. These laws provide a number of individual privacy rights and impose corresponding obligations on organizations doing business in these states. By way of example, California enacted the California Consumer Privacy Act ("CCPA"), effective January 1, 2020, which gives California residents expanded rights to access, correct, and delete their personal information, opt out of certain personal information sharing and disclosure, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that has increased the likelihood of, and risks associated with, data breach litigation. The CCPA may increase our compliance costs and potential liability. Further, the CPRA significantly amends the CCPA. The CPRA imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also creates a new California data protection agency, the California Privacy Protection Agency, which is authorized to issue substantive regulations and could result in increased privacy and information security enforcement and additional compliance investment and potential business process changes may be required. Similar laws have passed or have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. Further states have also enacted consumer health data privacy laws, including states without comprehensive consumer privacy laws, such as Nevada and Washington state. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition as a result of fines, penalties, litigation or other liabilities.

In the European Economic Area ("EEA"), the General Data Protection Regulation, ("GDPR") imposes stringent requirements for controllers and processors of personal data, including, for example, high standards for obtaining consent from individuals to process their personal data, robust disclosures to individuals and a strong individual data rights regime, short timelines for data breach notifications, limitations on retention and secondary use of information, significant requirements pertaining to health data and pseudonymized (i.e., key-coded) data and obligations when we contract third-party processors in connection with the processing of the personal data. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenue of the noncompliant company, whichever is greater. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States; in July 2020, the Court of Justice of the European Union ("CJEU") invalidated the EU-US Privacy Shield Framework ("Privacy Shield") under which personal data could be transferred from the EEA to US entities who had self-certified under the Privacy Shield scheme and imposed further restrictions on the use of standard contractual clauses. In March 2022, the U.S. and EU announced a new regulatory regime intended to replace the invalidated regulations with the Trans-Atlantic Data Privacy Framework (the "EU-U.S. DPF"). In July 2023, the European Commission adopted an adequacy decision in relation to the EU-U.S. DPF, allowing the EU-U.S. DPF to be utilized as a means of legitimizing EU-U.S. personal data transfers for participating entities. The EU-U.S. DPF may be subject to legal challenges from privacy advocacy groups or others, and the European Commission's adequacy decision regarding the EU-U.S. DPF provides that the EU-U.S. DPF will be subject to future reviews and may be subject to suspension, amendment, repeal, or

limitations to its scope by the European Commission. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, and/ or start taking enforcement action, we could suffer additional costs, complaints and/ or regulatory investigations or fines, and/ or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business, including but not limited to the General Data Protection Regulation in the European Union. Compliance with U.S. and foreign data privacy and security laws, rules and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or in some cases, impact our or our partners' or suppliers' ability to operate in certain jurisdictions. Each of these constantly evolving laws can be subject to varying interpretations. If we fail to comply with any such laws, rules or regulations, we may face government investigations and/or enforcement actions, fines, civil or criminal penalties, private litigation or adverse publicity that could adversely affect our business, financial condition and results of operations.

Our information technology systems, or those of any of our CROs, manufacturers, other contractors or consultants or potential future collaborators, may fail or suffer security breaches, which could result in a material disruption of our nimacimab development program, which could materially affect our results.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information, clinical trial data, and personal information, or collectively, "Confidential Information", of customers and our employees and contractors. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such Confidential Information.

There can be no assurance that our cybersecurity program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and Confidential Information. Despite the implementation of security measures as part of our cybersecurity program, our information technology systems and those of our current and any future CROs and other contractors, consultants and collaborators are vulnerable to attack and damage from computer viruses and malware (e.g., ransomware), misconfigurations, "bugs" or other vulnerabilities, cybersecurity threats, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the continued hybrid working environment, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. For example, during the second quarter of 2022, we were indirectly impacted by a cyberattack on our Phase 1 clinical supply contract manufacturer which delayed our production timeline and the initiation of enrollment in our Phase 1 clinical studies for SBI-100 OE to the fourth quarter of 2022. If such an event were to occur again in the future and cause interruptions in our operations or result in the unauthorized disclosure of or access Confidential Information, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. The loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We could also incur liability and the further development and commercialization of nimacimab could be delayed. In addition, we also rely on third parties to manufacture nimacimab, so similar events relating to their computer systems could also have a material adverse effect on our business. Some of the federal, state and foreign government requirements under data privacy and security laws include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our service providers or organizations with which we have formed strategic relationships. Notifications and follow-up actions related to a security breach could impact our reputation, cause us to incur significant costs, including legal expenses, harm customer confidence, hurt our expansion into new markets, cause us to incur remediation costs, or cause us to lose existing customers. Further, our insurance coverage may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems. To the extent that any disruption or security

breach were to result in violations of privacy and security laws, we could also be subject to significant fines, penalties or liabilities, which could adversely affect our business, financial condition, results of operations and prospects.

Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and may affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the ACA was enacted in the United States. Among the provisions of the ACA of importance to our potential product candidates, the ACA: established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; expanded eligibility criteria for Medicaid programs; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; created a new Medicare Part D coverage gap discount program; established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare Innovation at the Centers for Medicare and Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. It is unclear how any such challenges and the healthcare reform measures of the current administration, or any future presidential administration, will impact the ACA or our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, included reductions to Medicare payments to providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, unless additional congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, that was previously set at 100% of a drug's average manufacturer price, or AMP, and went into effect on January 1, 2024.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation 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 products. On August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (which began in 2023); and replaces the Part D coverage gap discount program with a new discounting program (which began in 2025). The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. On June 30, 2023, CMS issued new guidance detailing the requirements and parameters of the first round of price negotiations, to take place during 2023 and 2024, for products subject to the "maximum fair price" provision that would become effective in 2026. On August 29, 2023, HHS announced the list of the first ten drugs selected for price negotiations. In August 2024, following negotiation with the manufacturers of the selected drugs, HHS announced the negotiated prices for such drugs. Although the Medicare drug price negotiation program is currently subject to legal challenges, it is likely to have a significant impact on the pharmaceutical industry and could negatively affect our business and financial condition. CMS and HHS will continue to issue and update guidance as these programs are implemented.

At the state level, individual states in the United States are also increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including prescription drug affordability boards, 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. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

We cannot predict all of the ways in which future healthcare reform legislation or regulation could affect our business, particularly in light of the current presidential administration. We expect that these new laws and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved, which could have a material adverse effect on our results of operations and financial condition.

If product liability or state consumer protection act lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our products.

We face an inherent risk of product liability as a result of the clinical trials of our product candidates and will face an even greater risk if we commercialize our product candidates. For example, we may be sued if our product candidates allegedly cause injury or are found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product candidate, negligence, strict liability and a breach of warranties. Claims may be brought against us by clinical trial participants, patients or others using, administering or selling products that may be approved in the future, and could be asserted as product liability claims or under state consumer protection acts.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease the commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- initiation of investigations and enforcement actions by regulators;
- significant negative financial impact;
- the inability to commercialize our product candidates; and
- a decline in our stock price.

We currently hold $3,000,000 in product liability insurance coverage in the aggregate. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our product candidates. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts, which could have a material adverse effect on our business, results of operations and financial condition.

We and any of our potential future collaborators will be required to report to regulatory authorities if any of our approved products cause or contribute to adverse medical events, and any failure to do so would result in sanctions that would materially harm our business.

The FDA and foreign regulatory authorities require that we and any of our potential future collaborators report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We and any of our potential future collaborators or CROs may fail to report adverse events within the prescribed timeframe. If we or any of our potential future collaborators or CROs fail to comply with such reporting obligations, the FDA or a foreign regulatory authority could take action, including sanctions, criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products, which could have a material adverse effect on our business, results of operations and financial condition.

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

We are exposed to the risk that our employees and independent contractors, including principal investigators, CROs, consultants and vendors may engage in misconduct or other improper or illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate: (1) the laws and regulations of the FDA and other regulators and other similar regulatory requirements, including those laws that require the reporting of true, complete and accurate information to such authorities, manufacturing standards, (2) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad, or (3) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. Sales, marketing and other business arrangements in the healthcare industry are also subject to extensive laws intended to prevent fraud, 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. In addition, during the course of our operations our directors, executives, and employees may have access to material, nonpublic information regarding our business, our results of operations, or potential transactions we are considering. We may not be able to prevent a director, executive, or employee from trading in our common stock on the basis of, or while having access to, material, nonpublic information. 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. In addition, 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 and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We are currently subject to lawsuits, and in the future may be subject to additional lawsuits, that could divert its resources and result in the payment of significant damages and other remedies.

From time to time, the Company may be subject to litigation claims through the ordinary course of its business operations or otherwise, regarding, among other things, intellectual property rights matters, employment matters and tax matters. Litigation to defend the Company against claims by third parties, or to enforce any rights that the Company may have against third parties, may be necessary, which could result in substantial costs and diversion of the Company's resources, causing a material adverse effect on its business, financial condition and results of operations. Given the nature of the Company's business, it is, and may from time to time in the future be, party to various, and at times numerous, legal, administrative and regulatory inquiries, investigations, proceedings and claims that arise in the ordinary course of business, as well as potential class action lawsuits. For example, we are a party to the Cunning Lawsuit, a legal proceeding with a former employee alleging, among other things, wrongful termination, violation of whistleblower protections under the Sarbanes-Oxley Act of 2002, and retaliation under California law. While the outcome of the Cunning Lawsuit remains uncertain, including the final amount of the loss and loss recoveries, if any, there is a potential for the outcome of the Cunning Lawsuit to require payment of significant monetary damages. Further, to date, the Cunning Lawsuit has diverted management’s attention and required significant inputs of management’s time and resources. In addition, in late 2025 and early 2026, we and certain of our officers and directors were sued in a putative class action lawsuit and a related stockholder derivative lawsuit based on allegedly false and misleading statements related to nimacimab. We may be the target of additional litigation of this type in the future. Such litigation could result in substantial costs and a diversion of management’s attention and resources, which could harm our business.

Because the outcome of such legal matters is inherently uncertain, if one or more of such legal matters were to be resolved against the Company for amounts in excess of management's expectations or any applicable insurance coverage or indemnification right, the Company's results of operations and financial condition could be materially adversely affected. Any litigation to which the Company is a party may result in an onerous or unfavorable judgment that may not be reversed upon appeal, or in payments of substantial monetary damages or fines, the posting of bonds requiring significant collateral, letters of credit or similar instruments, or the Company may decide to settle lawsuits on similarly unfavorable terms. Moreover, the Company cannot be sure that the remedies available to it at law or under contract, will be sufficient in amount, scope or duration to fully or partially offset any such possible liabilities. Any of these factors, individually or in the aggregate, could have a material adverse effect on the Company's business, results of operations, cash flows or liquidity. For a description of certain currently pending legal and regulatory proceedings, including the Cunning Lawsuit and the putative class action lawsuit and related stockholder derivative lawsuit, see Note 12 to the Notes to the consolidated financial statements of the Company included in Part IV, Item 15 of this Annual Report.

The increasing use of social media and artificial intelligence-based platforms presents new risks and challenges.

Social media is increasingly being used to communicate about nimacimab, technologies and programs, and the diseases nimacimab is designed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to comment on the effectiveness of a product candidate or to report an alleged adverse event. When such disclosures occur, there is a risk that we fail to monitor and comply with applicable adverse event reporting obligations or we may not be able to defend ourselves or the public’s legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal data of our employees, clinical trial participants and others. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face overly restrictive regulatory actions or incur other harm to our business.

Additionally, artificial intelligence ("AI")-based solutions are increasingly being used in the biotechnology and biopharmaceutical industries, and as with many developing technologies, presents risks and challenges to our business. We and our contractors or third parties on which we rely may use AI solutions, which may give rise to liability, cause the loss or inadvertent release of data or intellectual property, result in reputational harm, or lead to outcomes with unintended biases or other consequences. AI systems may produce incorrect, incomplete, misleading or non-reproducible outputs (including "hallucinations"), may incorporate biases, and may be difficult to validate, explain, audit or control. Errors or failures could adversely affect the integrity of our research, clinical trials, regulatory submissions, product quality, patient safety, timelines and costs, and could lead to regulatory scrutiny or enforcement. The misuse of AI solutions could also result in unauthorized access and use of personal data of our employees, clinical trial participants, collaborators or other third parties. The legal and regulatory landscape for AI is rapidly evolving in the U.S. and internationally (including in the European Union), and may require us to implement additional governance, documentation, validation, monitoring, cybersecurity and compliance measures and incur significant costs, or may limit or delay our ability to use AI in our operations. Any of these events could have a material adverse effect on our business, prospects, operating results, and financial condition and could adversely affect the price of our common stock.

Risks Related to Our Intellectual Property

Our success depends on our ability to protect our intellectual property and our proprietary technologies, and if we are unable to protect our intellectual property and technologies, our business will suffer.

Our commercial success depends in part on our ability to obtain and maintain intellectual property protection for our product candidates, proprietary technologies, and their uses, as well as our ability to operate without infringing the proprietary rights of others. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates, proprietary technologies and their uses that are important to our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around, or invalidated by third parties. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. This failure to obtain effective intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the pharmaceutical and biotechnology space has emerged in the United States. The relevant patent laws and their interpretation outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our technology or product candidates and could affect the value of such intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions and improvements. We cannot guarantee that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may file in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our products, the methods of use or manufacture of those products. Moreover, even our issued patents do not guarantee us the right to practice our technology in relation to the commercialization of our products. Patent and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and practicing our proprietary technology, and our issued patents may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or could limit the term of patent protection that otherwise may exist for our product candidates. In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies that are outside the scope of the rights granted under any issued patents. For these reasons, we may face competition with respect to our product candidates even if our patent applications are granted.

Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate 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. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include but are not limited to the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our potential product candidates;
- there may be significant pressure on the U.S. government, other governmental authorities, and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

The patent prosecution process is also expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, suppliers, contractors, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, which could have a material adverse effect on our business and prospects.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be material and adversely affected.

The patent position of biopharmaceutical companies is generally highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our product candidates or which effectively prevent others from commercializing competitive product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own currently or in the future 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. Any issued patents that we own may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether 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 which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. Our patents may be challenged in the courts or patent offices in the United States and abroad and may be narrowed or invalidated as a result of challenges by third parties. We may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review, or PGR, and inter partes review, or IPR, or other similar proceedings challenging our owned patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our product candidates 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, our patents may become subject to post-grant challenge proceedings, such as oppositions in a foreign patent office, which challenge our priority of invention or other features of patentability with respect to our patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity or 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 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. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates, which could have a material adverse effect on our business and prospects.

We may be involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court.

Competitors may infringe our intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own is not valid, is unenforceable and/or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including but not limited to lack of novelty, obviousness, written description or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

Third parties may also raise similar invalidity claims before the USPTO or patent offices abroad, even outside the context of litigation. Such mechanisms include re-examination, PGR, IPR, 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 platform, 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. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of a patent claim. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates or other intellectual property that we may develop. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. 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.

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

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

- others may be able to develop products that are similar to our product candidates but that are not covered by the claims of the patents that we own;
- we might not have been the first to make the inventions covered by the issued patents or patent application that we own;
- we might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

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

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, oppositions, reexaminations, IPR proceedings and PGR proceedings before the USPTO and/or corresponding foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, we may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. There is also no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;

- prevent us from commercializing any of our product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Although no third party has asserted a claim of patent infringement against us as of the date of this Annual Report, others may hold proprietary rights that could prevent nimacimab or any of our future product candidates from being marketed once approved. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our products or processes could subject us to potential liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or market our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or our future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could delay or prevent us from developing and commercializing our product candidates, which could harm our business, financial condition and operating results. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

Derivation proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party.

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

Changes in U.S. patent law, or laws in other countries or jurisdictions, could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing pharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

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

If we do not obtain patent term extension for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, if obtained, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. 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.

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

Patents are of national or regional effect. Filing, prosecuting and defending patents in all countries throughout the world could be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with 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 many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights. As an example, as of June 2023, European patent applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court, or UPC. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC may be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who ratified the Unitary Patent Court Agreement. The option of a Unitary Patent will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty. Proceedings to enforce our patent 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. 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.

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

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our product candidates, proprietary technologies, and their uses. While we will endeavor to try to protect our product candidates, proprietary technologies, and their uses, with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time consuming, expensive, and unpredictable.

Further, geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. Changes in U.S. trade policy, including the imposition of new or increased tariffs as well as retaliatory measures by other countries, could adversely affect our patent strategy, such as where we choose to file, maintain, or enforce our patents. Also, if we are required to move our research or manufacturing activities to new regions, this may expose us to jurisdictions with weaker intellectual property enforcement, differing patent eligibility standards, or greater risk of compulsory licensing. These factors could compromise the protection or value of our proprietary technologies, including our core patents and related know-how. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or applications. We have systems in place to remind us to pay these fees, and we rely on our outside patent annuity service to pay these fees when due. Additionally, the USPTO and various foreign patent offices, require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business.

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

We rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and 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 United States are less willing or unwilling to protect trade secrets.

Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the pharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Risks Related to Our Common Stock

The trading price of our common stock has been volatile with substantial price fluctuations on heavy volume, which could result in substantial losses for purchasers of our common stock and existing stockholders.

Our stock price has been and, in the future, may be subject to substantial volatility. During the fiscal year ended December 31, 2025, the price per share of our common stock has ranged as low as $0.68 and as high as $5.75.

Furthermore, the stock market in general and the market for biopharmaceutical 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 common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- announcements relating to development, regulatory approvals or commercialization of our product candidates or those of competitors;
- results of clinical trials of our product candidates or those of our competitors;

- announcements by us or our competitors of significant strategic partnerships or collaborations or terminations of such arrangements;
- actual or anticipated variations in our operating results and whether we have achieved key business targets;
- sales of our common stock, including sales by our directors and officers or specific stockholders;
- changes in, or our failure to meet, financial estimates by us or by any securities analysts who might cover our stock;
- changes in securities analysts' buy and/or sell recommendations;
- general economic, political, or stock market conditions;
- conditions or trends in our industry;
- changes in laws or other regulatory actions affecting us or our industry;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- capital commitments;
- investors' general perception of our company, our business, and our prospects;
- disputes concerning our intellectual property or other proprietary rights; and
- recruitment or departure of key personnel.

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. For example, in late 2025 and early 2026, we and certain of our officers and directors were sued in a putative class action lawsuit and a related stockholder derivative lawsuit based on allegedly false and misleading statements related to nimacimab. Such litigation, could cause us to incur substantial costs and divert management's attention and resources from our business.

Our failure to meet the continued listing requirements of the Nasdaq, including the minimum closing bid price requirement, could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of the Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. As of the date of this Annual Report, our common stock has had a closing bid price of less than $1.00 per share for 39 consecutive trading days. As a result, because the closing bid prices is less than $1.00 for 30 consecutive trading days, we may receive a letter from NASDAQ stating that our common stock will be delisted unless we are able to regain compliance with the NASDAQ Listing Rule requiring that we maintain a closing bid price for our common stock of at least $1.00 per share. We cannot guarantee that our common stock will continue to trade above $1.00 per share in the near term or otherwise meet the NASDAQ listing requirements and therefore our common stock may in the future be subject to delisting.

If our common stock were no longer listed on NASDAQ, investors might only be able to trade on one of the over-the-counter markets, including the OTC Bulletin Board® or in the Pink Sheets® (a quotation medium operated by Pink Sheets LLC). This would impair the liquidity of our common stock, not only in the number of shares that could be bought and sold at a given price, which might be depressed by the relative illiquidity, but also through delays in the timing of transactions and reduction in media coverage. In addition, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- a limited amount of news and analyst coverage for us; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the NASDAQ minimum bid price requirement or prevent future non-compliance with NASDAQ's listing requirements.

We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation, if any, in the price of our common stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to control or significantly influence all matters submitted to stockholders for approval.

Our executive officers, directors and greater than 5% stockholders, in the aggregate, owned approximately 36% of our outstanding common stock as of December 31, 2025. As a result, such persons, acting together, have the ability to control or significantly influence all matters submitted to our stockholders for approval, including the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

The consent rights of our January PIPE Investors pursuant to the January 2024 PIPE SPA may adversely affect our ability to pursue certain strategic transactions.

Under the terms of the securities purchase agreement (the "January 2024 PIPE SPA") entered into with certain investors ("the January 2024 PIPE Investors") in connection with the January PIPE Financing, so long as the January 2024 PIPE Investors continue to beneficially own in the aggregate at least 40% of the securities issued in the January 2024 PIPE Financing (such securities, the "Closing Securities"), the Company may not transfer, license (other than in the ordinary course of business), encumber, or sell a royalty interest in any intellectual property relating to nimacimab unless the Company obtains the written consent of Qualified Investors that, together with their respective affiliates, beneficially own at least a majority of the then outstanding Closing Securities owned by the Qualified Investors and their respective affiliates. The term "Qualified Investors" means any January 2024 PIPE Investor that, together with its affiliates, continues to own at least 80% of the Closing Securities originally purchased by it under the January 2024 PIPE SPA. As of the date of this Annual Report, to our knowledge, the January 2024 PIPE Investors own more than 40% of the Closing Securities. However, the views and interests of the Qualified Investors may differ or divulge from those of us and our other stockholders. As a result, the consent rights of our January 2024 PIPE Investors may have the effect of delaying, deferring or preventing us from pursuing certain strategic transactions that would directly or indirectly result in the transfer of such intellectual property, which may include, among other things, licensing of such intellectual property and/or a merger, consolidation, takeover or other business combination involving us, or discouraging a potential third party from pursuing such a transaction with us, even if such a transaction would benefit other stockholders.

We issued pre-funded warrants as part of our January 2024 financing, which may cause additional dilution to our shareholders.

In January 2024, we closed a private placement transaction and issued pre-funded warrants to purchase a total of 9,978,739 shares of our common stock, of which 3,677,879 have been exercised and 6,300,860 are currently outstanding. Each pre-funded warrant is exercisable for $0.001 per share of common stock underlying such pre-funded warrant. To the extent the pre-funded warrants are exercised, additional shares will be issued and such issuance would dilute existing shareholders and increase the number of shares eligible for resale in the public market.

We have a substantial number of authorized common shares available for future issuance that could cause dilution to our stockholders' interest and adversely impact the rights of the holders of our shares.

We have a total of 100,000,000 shares of common stock authorized for issuance and up to 200,000 shares of preferred stock with the rights, preferences and privileges that our Board may determine from time to time. As of December 31, 2025, we have reserved; 4,528,555 shares for issuance upon the exercise of outstanding options, 492,488 shares for issuance upon the vesting of outstanding restricted stock units, 148,119 shares for issuance under our omnibus equity incentive plan, 142,500 shares for issuance under our inducement incentive plan, 328,427 shares for issuance under our 2022 employee stock purchase plan, and 9,390,042 shares for issuance upon the exercise of outstanding warrants. As of December 31, 2025, we had no outstanding preferred stock. As of December 31, 2025, we had 53,995,310 shares of common stock unreserved and available for issuance. We may seek financing that could result in the issuance of additional shares of our capital stock and/or rights to acquire additional shares of our capital stock. We may also make acquisitions that result in issuances of additional shares of our capital stock. Those additional issuances of capital stock would result in a significant reduction of your percentage interest in us. Furthermore, the book value per share of our common stock may be reduced. This reduction would occur if the exercise price of any issued warrants, the conversion price of any convertible notes is lower than the book value per share of our common stock at the time of such exercise or conversion.

The addition of a substantial number of shares of our common stock into the market or by the registration of any of our other securities under the Securities Act, may significantly and negatively affect the prevailing market price for our common stock. The future sales of shares of our common stock issuable upon the exercise of outstanding warrants may have a depressive effect on the market price of our common stock, as such warrants would be more likely to be exercised at a time when the price of our common stock is greater than the exercise price.

The issuance of shares upon exercise of outstanding warrants and options may cause immediate and substantial dilution to our existing stockholders.

If the price per share of our common stock at the time of exercise of any warrants, options, or any other convertible securities is in excess of the various conversion or exercise prices of these convertible securities, conversion or exercise of these convertible securities would have a dilutive effect on our common stock. As of December 31, 2025, we had outstanding (i) warrants to purchase up to 9,390,042 shares of our common stock at exercise prices ranging from $0.001 to $288 per share, (ii) options to purchase up to 4,528,555 shares of our common stock at exercise prices ranging from $1.06 to $76.25 per share, (iii) 492,488 unreleased restricted stock units exchangeable for shares of our common stock upon vesting. Further, any additional financing that we secure may require the granting of rights, preferences or privileges senior to those of our common stock and which result in additional dilution of the existing ownership interests of our common stockholders.

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

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. In general, an "ownership change" occurs if the aggregate stock ownership of one or more stockholders or groups of stockholders who own at least 5% of a corporation's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. If we experience ownership changes as a result of future transactions in our stock, our ability to use our net operating loss carryforwards and other tax attributes to offset U.S. federal taxable income may be subject to further limitations, which could potentially result in increased future tax liability to us.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

We are a smaller reporting company within the meaning of the Securities Act, and if we continue to decide to take advantage of certain exemptions from various reporting requirements applicable to smaller reporting companies, our common stock could be less attractive to investors.

We are a smaller reporting company. For so long as we qualify as a smaller reporting company, we will have the option to take advantage of certain exemptions from various reporting and other requirements that are applicable to other public companies that are not smaller reporting companies, including, but not limited to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. In addition, for as long as we are deemed neither a large accelerated filer nor accelerated filer, we may continue to use the exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act.

We will remain a smaller reporting company and non-accelerated filer until we have a public float of $700 million or more as of the last business day of our most recently completed second fiscal quarter and annual revenues of less than $100 million, or a public float of $250 million or more as of the last business day of our most recently completed second fiscal quarter and annual revenues of $100 million or more. We will need to reassess, as of June 30, 2026, whether we will continue to qualify as a smaller reporting company and a non-accelerated filer for filings beyond the fiscal year ending December 31, 2025. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

General Risk Factors

We and any of our third-party manufacturers or suppliers may use potent chemical agents and hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.

We and any of our third-party manufacturers or suppliers will use biological materials, potent chemical agents and may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety of the environment. Our operations and the operations of our third-party manufacturers and suppliers also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. In the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

Although we maintain workers' compensation insurance for certain costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for toxic tort claims that may be asserted against us in connection with our storage or disposal of biologic, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations could be subject to terrorism, war, earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, health epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We rely on third- party suppliers and manufacturers to produce our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers and manufacturers were affected by a man-made or natural disaster or other business interruption, which could have a material adverse effect on our business. For example, the COVID-19 pandemic and government measures taken in response had a significant impact, both direct and indirect, on businesses and commerce, resulting in delays and interruptions in our drug manufacturing, nonclinical activities, clinical trials, review and approval timelines, and our discovery and development pipeline. A resurgence or the widespread occurrence of another deadly illness could adversely affect our business, operations and financial results. In addition, our corporate headquarters is located in San Diego, California near major earthquake faults and fire zones, and the ultimate impact on us of being located near major earthquake faults and fire zones and being consolidated in a certain geographical area is unknown. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Unfavorable global economic conditions could adversely affect our business, financial condition and stock price.

The global credit and financial markets are currently, and have from time to time, experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, fluctuating interest and inflation rates, fluctuations in currency exchange rates, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in unemployment rates and uncertainty about economic stability. For example, while the Federal Reserve recently raised interest rates multiple times in response to concerns about inflation, the Federal Reserve has indicated that it intends to closely monitor market conditions to determine whether it will consider making additional adjustments to short-term interest rates during the remainder of 2025. Higher interest rates, coupled with reduced government spending and volatility in financial markets may increase economic uncertainty and affect consumer spending. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military and/or geopolitical conflict, impact of a prolonged potential U.S. government shutdown, terrorism or other geopolitical events, with the potential to result in extreme volatility in the global capital markets and further global economic consequences, including the imposition of tariffs, disruptions of the global supply chain and energy markets. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability.

A future recession or market correction or other significant geopolitical events could materially affect our business and the value of our common stock. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, including as a result of political unrest or war, or if adverse developments are experienced by financial institutions, it may cause short-term liquidity risk and also make any necessary debt or equity financing more difficult, more costly, more onerous with respect to financial and operating covenants and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may be adversely affected by the foregoing risks, which could directly affect our ability to attain our operating goals on schedule and on budget.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export and import control laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, and anti-corruption and anti-money laundering laws and regulations, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, clinical research organizations, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector.

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. We can be held liable for the corrupt or other illegal activities of our employees, agents, clinical research organizations, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Furthermore, U.S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments, and persons targeted by U.S. sanctions. U.S. sanctions that have been or may be imposed as a result of military conflicts in other countries may impact our ability to continue activities at clinical trial sites within regions covered by such sanctions. These and any additional sanctions and export controls, as well as any economic countermeasures by the governments of Russia or other jurisdictions, could adversely impact our ability to continue activities at clinical trial sites within regions covered by such sanctions or directly or indirectly disrupt our supply chain. 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.

Changes to tariff and import/export regulations, and trade disputes between the United States and other jurisdictions may have a negative effect on global economic conditions and our business, financial results and financial condition.

The United States and other foreign jurisdictions may change customs regulations or tariff rates that are applied to our imports or exports at any time. Tariff changes are difficult to predict and may cause us material short-term or long-term cost fluctuations. In addition to the use of tariffs as a revenue-generating tool, the current administration in the United States has used tariffs more robustly in pursuing government policy. When increases are made to U.S. duty rates or tariffs, reciprocal action by other countries sometimes occurs, and any such increases could impact the price of our products and cause a decline in the demand for our products. In addition to duties and tariffs, any actions taken by the United States or by foreign countries to further implement trade policy changes, including limiting foreign investment or trade, increasing regulatory requirements, or other actions that impact our ability to obtain necessary licenses or approvals could negatively impact our business. These actions are unpredictable, and any of them could also have a material adverse effect on global economic conditions and the stability of global financial markets, significantly reduce global trade, restrict our access to suppliers or customers, and have a material adverse effect on our business, financial condition and results of operations.

If securities or industry analysts do not publish research or reports or publish unfavorable research or reports about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. If securities or industry analysts do not continue coverage of our company, the trading price for our stock would be negatively impacted. In the event one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

We engage in transactions with related parties which present possible conflicts of interest that could have an adverse effect on us.

We have entered, and may continue to enter, into transactions with affiliates and other related parties for a number of different services. Such transactions may not have been entered into on an arm's-length basis, and we may have achieved more or less favorable terms because such transactions were entered into with our related parties. The details of certain of these transactions are set forth in "Certain Relationships and Related Party Transactions". Related party transactions create the possibility of conflicts of interest with regard to our management.

Such conflicts could cause an individual in our management to seek to advance his or her economic interests or the economic interests of certain related parties above ours. Further, the appearance of conflicts of interest created by related party transactions could impair the confidence of our investors. Our audit committee reviews these transactions. Notwithstanding this, it is possible that a conflict of interest could have a material adverse effect on our liquidity, results of operations and financial condition.

Changes in tax laws may impact our financial condition and results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, or interpreted, changed, modified or applied adversely to us, any of which could adversely affect our business operations and financial performance. We are currently unable to predict whether such changes will occur and, if so, the ultimate impact on our business. To the extent that such changes have a negative impact on us, our suppliers or our customers, including as a result of related uncertainty, these changes may materially and adversely impact our business, financial condition, results of operations and cash flows.

We are currently subject to, and in the future could be subject to additional, securities class action litigation.

In the past, securities class action litigation has often been brought against companies following a decline in the market price of their securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. For example, in late 2025 and early 2026, we and certain of our officers and directors were sued in a putative class action lawsuit and a related stockholder derivative lawsuit based on allegedly false and misleading statements related to nimacimab. We may be the target of additional litigation of this type in the future. Such litigation could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of Sarbanes-Oxley, our management is required to annually report upon the effectiveness of our internal control over financial reporting. However, as a smaller reporting company and a non-accelerated filer and in accordance with new SEC rules effective in 2020, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 for as long as we are not deemed an "accelerated filer" or "large accelerated filer". The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Although we have determined that our internal control over financial reporting was effective as of December 31, 2025, we cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begin its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

We incur significant costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, Sarbanes-Oxley, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of Sarbanes-Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory "say on pay" voting requirements that apply to us. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

The rules and regulations applicable to public companies have increased and may continue to increase our legal and financial compliance costs and to make some activities more time consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will increase our net loss and may require us to reduce costs in other areas of our business. For example, these rules and regulations make it more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through equity offerings, such as public equity offerings and offerings under the Sales Agreement, and debt financings or other capital sources, including collaborations, licenses and other similar arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or near term operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, which could have a material adverse effect on our business and operations, as well as the trading price of our common stock.

In addition, if we raise funds through future collaborations, licenses and other similar arrangements, 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, which may have a material adverse effect on our business, prospects and may reduce the value of our common stock.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic and/or transformative transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of intellectual property, products or technologies. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction could be material and could disrupt our business or change our business profile, focus or strategy significantly. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Future transactions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits and could delay our timelines or otherwise adversely affect our business. Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

We maintain a cyber risk management program designed to identify, assess, manage, mitigate, and respond to cybersecurity threats. This program, in conjunction with the Company's enterprise risk management assessment processes, addresses cybersecurity risks to the corporate information technology ("IT") environment including systems, hardware, software, data, people, and processes.

The underlying processes and controls of our cyber risk management program are designed based on standards for cybersecurity and information technology, including the National Institute of Standards and Technology ("NIST") Cybersecurity Framework ("CSF"). Skye has an annual assessment performed by a third-party specialist of its cyber risk management program against the NIST CSF. The annual risk assessment identifies, quantifies, and categorizes significant cyber risks. In addition, the Company, in conjunction with the third-party cyber risk management specialists develop a risk mitigation plan to address identified risks and, where necessary, remediate potential issues identified through the annual assessment process.

In addition, we maintain an information security policy that covers safeguarding and managing confidential information, handling personal and company-sensitive data, managing access on/off-boarding and user accounts, acceptable use and IT change management to help govern the processes put in place by management designed to protect Skye's IT assets, data, and services from threats and vulnerabilities. We partner with industry recognized cybersecurity providers leveraging third-party technology and expertise. We and our cybersecurity partners maintain an IT assets inventory, identity access management controls including restricted access of privileged accounts, physical security measures at Company facilities, information protection/detection systems including maintenance of firewalls and anti-malware tools, network and data traffic monitoring and automated alerting, capacity management, industry-standard encryption protocols, formalized change management processes, critical data backups infrastructure maintenance, incident response, cybersecurity strategy, and cyber risk advisory, assessment and remediation.

Our management team is responsible for oversight and administration of our cyber risk management program, and for informing senior management and other relevant stakeholders regarding the prevention, detection, mitigation, and remediation of cybersecurity incidents. Our management team has experience selecting, deploying, and overseeing cybersecurity technologies, initiatives, and processes directly or via selection of strategic third-party partners, and relies on threat intelligence as well as other information obtained from governmental, public, or private sources, including external consultants engaged by Skye for strategic cyber risk management, advisory and decision making.

We have implemented third-party risk management processes to manage the risks associated with reliance on vendors, critical IT service providers, and other third-parties that may lead to a service disruption or an adverse cybersecurity incident. This includes processes for performing due diligence upon on-boarding.

The audit committee (the "Audit Committee") of our Board of Directors oversees our cybersecurity risk exposures and the steps taken by management to monitor and mitigate cybersecurity risks. The cybersecurity stakeholders, including management assigned with cybersecurity oversight responsibility and/or third-party consultants providing cyber risk services brief the Audit Committee on cyber vulnerabilities identified through the risk management process, the effectiveness of our cyber risk management program, and the emerging threat landscape and new cyber risks on at least an annual basis. This includes updates on our processes to prevent, detect, and mitigate cybersecurity incidents. In addition, cybersecurity risks are reviewed by our Board at least annually, as part of our corporate risk oversight processes.

We face risks from cybersecurity threats that could have a material adverse effect on its business, financial condition, results of operations, cash flows or reputation. We acknowledge that the risk of cyber incidents is prevalent in the current threat landscape and that a future cyber incident may occur in the normal course of its business. However, prior cybersecurity incidents have not had a material adverse effect on our business, financial condition, results of operations, or cash flows. We proactively seek to detect and investigate unauthorized attempts and attacks against IT assets, data, and services, and to prevent their occurrence and recurrence where practicable through changes or updates to internal processes and tools and changes or updates to the service delivery; however, potential vulnerabilities to known or unknown threats will still remain and we may not be able to prevent security incidents in the future. Further, there is increasing regulation regarding responses to cybersecurity incidents, including reporting to regulators, investors, and additional stakeholders, which could subject us to additional liability and reputational harm. In response to such risks, we have implemented initiatives such as implementation of the cybersecurity risk assessment process and development of an incident response plan. See Item 1A. "Risk Factors" for more information on cybersecurity risks.

Item 2. Properties.

We lease our principal executive offices and corporate offices, which are located at 11250 El Camino Real Suite 100, San Diego, CA 92130. Our lease for this facility expires on October 31, 2026. We believe that our facilities are adequate to meet our current needs, and that suitable alternative spaces will be available in the future on commercially reasonable terms, if required.

Item 3. Legal Proceedings.

For a description of material legal proceedings, see Note 12 to the accompanying consolidated financial statements.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information.

Our common stock has been quoted on the Nasdaq Global Select Market under the symbol "SKYE". On March 9, 2026, the last reported sale price of our common stock on the Nasdaq Global Select Market was $0.72 per share.

Stockholders. As of March 9, 2026, there were 181 stockholders of record. The number of stockholders of record does not include beneficial owners of our common stock, whose shares are held in the names of various dealers, clearing agencies, banks, brokers and other fiduciaries.

Dividends. We have never declared or paid a cash dividend on our common stock. We do not expect to pay cash dividends on our common stock in the foreseeable future. We currently intend to retain our earnings, if any, for use in our business. Any dividends declared in the future will be at the discretion of our Board and subject to any restrictions that may be imposed by our lenders.

Performance Graph. We were a smaller reporting company, as defined by Rule 12b-2 of the Exchange Act as of December 31, 2025, and are not required to provide a performance graph.

Recent Sales of Unregistered Securities. None.

Issuer Purchases of Equity Securities. None.

Item 6. [Reserved]

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements for the years ended December 31, 2025 and 2024 together with notes thereto. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including, but not limited, to those set forth under "Risk Factors" and elsewhere in this Annual Report.

Unless otherwise provided in this Annual Report, references to "we," "us," "our" and "Skye" in this discussion and analysis refer to Skye Bioscience, Inc., a Nevada corporation, together with its wholly owned subsidiaries, Nemus, a California corporation, SKYE Bioscience Pty Ltd ("SKYE Bioscience Australia"), an Australian proprietary limited company, Emerald Health Therapeutics, Inc. (EHT) a corporation governed by the Business Corporations Act (British Columbia), and Bird Rock Bio Sub, Inc. ("BRB"), a Delaware corporation.

Overview

We are a clinical stage biotechnology company pioneering next-generation molecules that modulate G-protein-coupled receptors ("GPCRs") to treat obesity, overweight, and related conditions. Our lead candidate, nimacimab, is a peripherally restricted negative allosteric modulating antibody targeting cannabinoid receptor 1 ("CB1")—a key GPCR involved in metabolic regulation that is administered as a subcutaneous injectable initially for the treatment of obesity and overweight.

In October of 2025, we reported topline data from our Phase 2a clinical trial, CBeyond™, for nimacimab and in February 2026 we reported interim results from the combination cohort of the 26 week extension study. In response to the trial results, we have shifted focus to a combination therapy strategy while continuing to evaluate the monotherapy as a potential standalone or second-line therapy if efficacy can be achieved with higher doses. In March 2026, we initiated an expansion study (Part C) of the CBeyond Phase 2a trial to assess preliminary safety and pharmacokinetic (PK) profile of nimacimab administered intravenously (IV). The expansion study will comprise two cohorts of nimacimab monotherapy (400 mg IV and 600 mg IV) compared to placebo administered weekly over 15 weeks (16 doses), with a 12 week follow up period.

On August 18, 2023, we completed a strategic transaction to acquire a clinical asset pursuant to an Agreement and Plan of Merger and Reorganization, dated as of August 15, 2023, by and among the Company, Bird Rock Bio, Inc. and Aquila Merger Sub, Inc., pursuant to which Aquila Merger Sub, Inc. merged with and into Bird Rock Bio, Inc. with Bird Rock Bio, Inc. surviving as a wholly owned subsidiary of the Company (the "BRB Acquisition"). The purpose of the BRB Acquisition was to acquire BRB's clinical asset, nimacimab, an antibody targeting the CB1 receptor, for development to treat metabolic, inflammatory, and fibrotic conditions.

In January 2024 and March 2024, we completed two private placement equity transactions (the "January and March PIPE Financings") with institutional accredited investors, in which we raised combined net aggregate proceeds of $83,556,563. The net proceeds raised from the January and March PIPE Financings, along with the reallocation of funds from the elimination of our ocular program (as described below) have allowed us to fund our clinical trial of nimacimab for obesity through top-line Phase 2a data, complete process intensification manufacturing activities along with drug substance and product manufacturing work needed for our Phase 2b study and enable us to expand upon our metabolic program with our other research and development efforts. Our cash runway currently excludes the Phase 2b clinical study, additional manufacturing activities expected to complete the Phase 2b resupply and costs related to future registrational studies.

In April 2024, Skye uplisted to the Nasdaq Global Market® stock exchange from the OTCQB.

On May 10, 2024, we entered into an Equity Distribution Agreement (the “ATM Agreement”) with Piper Sandler & Co, as the sales agent (the “Sales Agent”), under which we may, from time to time, sell up to $100,000,000 of shares of our common stock through the Sales Agent (the “ATM Offering”). We are not obligated to, and we cannot provide any assurances that we will, make any sales of the shares under the ATM Agreement. We will pay the Sales Agent a commission for their services in acting as agent in the sale of common stock in an amount up to 3% of the gross sales price per share sold. We have not issued any shares under the ATM Offering.

In June 2024, we completed our Phase 2a double-masked randomized, placebo-controlled trial of SBI-100 Ophthalmic Emulsion (“SBI-100 OE”) in 56 patients with elevated intraocular pressure ("IOP") diagnosed with primary open-angle glaucoma or ocular hypertension. The primary endpoint evaluated the change in diurnal IOP in the treated arm vs. placebo over 2 weeks. The study did not achieve a statistically significant improvement in IOP over placebo. As a result, we eliminated our ocular program and strategically redirected our efforts and capital resources to our metabolic program. We have also terminated our license agreement with the University of Mississippi and other vendor contracts related to the manufacture, development, and sublicense of SBI-100 OE.

In August of 2024, the Convertible Note (as defined in Note 6 to the accompanying consolidated financial statements) with a principal value of $5,000,000, was converted into 968,973 shares of our common stock.

During the fourth quarter of 2024, we were successful in our appeal in the Ninth Circuit Court of Appeals (the "Ninth Circuit") of the judgment of a material litigation matter, which has been remanded to the District Court for a new trial, and the bond related to the judgement was exonerated, allowing us to recover $9,000,000 in restricted cash. Additionally, in a related case with our insurance carrier, we collected $2,000,000 during the fourth quarter of 2024. The recovered funds were reallocated to further our clinical pipeline and extended our cash runway.

We were incorporated under the laws of the State of Nevada on March 16, 2011, and our headquarters are based in San Diego, CA. Since our incorporation, we have devoted substantially all of our efforts to building our product portfolio through the acquisition of clinical assets and licensing agreements, carrying out research and development, building infrastructure and raising capital.

Financial Overview

Revenues

To date, we have not generated any revenue. We do not expect to receive any revenue from our lead drug candidate, nimacimab, or any future drug candidates that we develop unless and until we obtain regulatory approval for, and commercialize, our drug candidates or generate revenue from collaborative agreements with third parties.

Research and Development Expenses

During the year ended December 31, 2025, we incurred $42,361,879 in research and development expenses primarily related to our efforts in conducting the Phase 2a clinical trial of nimacimab for obesity and manufacturing costs in preparation of our Phase 2b trial. During the year ended December 31, 2024, we incurred $18,701,694 in research and development expenses primarily related to our efforts in conducting the Phase 2a clinical trial of nimacimab for obesity, manufacturing and residual costs from our legacy Phase 2a SBI-100 OE clinical trial.

We expect that our ongoing research and development expenses will consist of costs incurred for the development of our drug candidate, nimacimab, or any future drug candidates, including, but not limited to:

- employee-related expenses, which include salaries, benefits and stock-based compensation;
- payments to third party contract research organizations and investigative sites;
- payments to third party manufacturing organizations and consultants; and
- payments to third parties related to our discovery research and development efforts to build our pipeline.

We expect to incur future research and development expenditures to support our preclinical, nonclinical, and clinical studies. Preclinical and nonclinical activities include early discovery efforts with novel molecules, laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess safety and efficacy.

The process of conducting the necessary clinical research to obtain regulatory approval is costly and time consuming and the successful development of our drug candidate, nimacimab, and any future drug candidate is highly uncertain. Our future research and development expenses will depend on the clinical success of nimacimab and any future drug candidates as well as ongoing assessments of the commercial potential of such drug candidates. In addition, we cannot forecast with any degree of certainty whether nimacimab or any future drug candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. We expect to incur increased research and development expenses in the future as we continue our efforts towards advancing our lead program for nimacimab.

General and Administrative Expenses

Our general and administrative expenses have fluctuated year-over-year as we have entered into various strategic acquisitions to restructure and reposition our company. Additionally, as a business in the early stages of drug development we are in the process of scaling our operations by hiring additional employees and building the infrastructure necessary to increase efficiencies. These initiatives have resulted in additional costs related to the implementation of certain systems, insurance, facilities, legal, tax and accounting costs. As a public company, we expect to incur additional expenses related to insurance, investor relations activities, legal and other administration and professional services to comply with the rules and regulations of the SEC, the Financial Industry Regulatory Authority ("FINRA") and Nasdaq. Other significant costs are expected to include legal fees relating to patent and corporate matters, business development costs and fees for consulting services. To incentivize our employees and be competitive to retain strong talent we issued additional equity awards in 2024, which have resulted in increased stock-based compensation expense. We also expect that certain general and administrative expenses which are commensurate with headcount, will continue to increase in the future in order to support our expected increase in research and development activities, including increased salaries, technology, facilities and other related costs.

Estimated Legal Contingency and Income from Insurance Recovery

The estimated legal contingency relates to a material litigation matter that was related to our former management team. As of December 31, 2023, we had posted an appellate bond that was collateralized by an irrevocable letter of credit equal to, $9,080,202, approximately 150% of the liability recorded on our balance sheet. During 2024, we were successful in our appeal of the judgment in the Ninth Circuit Court of Appeals and the case was remanded back to the District Court for a new trial, as a result of which we reduced the estimated legal contingency based on new key assumptions. The final amount of the loss and loss recoveries remains uncertain. We believe that it is at least reasonably possible that the estimated amount of the potential loss may change in the near term. As of December 31, 2025, the estimated legal contingency, including accrued legal expenses, is $2,069,067. See Note 12 to the accompanying consolidated financial statements for more information.

Additionally, in a related case with our insurance carrier, we collected $2,000,000 during the fourth quarter of 2024. The recovered funds were reallocated to further our general operations.

Other Expense

Other (income) expense primarily includes gains from installment payments related to the sale of Verdelite Sciences, Inc. ("VDL") and the sale of the Avalite Sciences, Inc. ("AVI") building (the "AVI building") in the first quarter of 2024, and interest expense. These expenses are offset by interest income earned on our cash and cash equivalent balances and short term investments.

Critical Accounting Estimates

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements and the reported amounts of income and expenses during the reporting period. On an on-going basis, management evaluates its estimates and judgments, including those related to accrued expenses, the percentage of completion as it relates to our clinical accruals, financing operations, contingencies, the fair value of assets acquired in the acquisitions, and litigation. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The most significant accounting estimates inherent in the preparation of our consolidated financial statements include estimates as to the appropriate carrying value of certain assets and liabilities which are not readily apparent from other sources. These accounting estimates are described at relevant sections in this discussion and analysis and in the notes to the consolidated financial statements included in this Annual Report. We believe that the following accounting estimates are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our consolidated financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing contracts and vendor agreements, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. We make estimates of our accrued and prepaid clinical expenses on a quarterly basis in our consolidated financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to contract research organizations ("CROs"), investigative sites in connection with clinical studies and to vendors related to product manufacturing and development of clinical supplies.

We base our expenses related to clinical study and trial costs on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows and expense recognition. Payments under some of these contracts depend on factors out of our control, such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, we may report amounts that are too high or too low in any particular period. There have been no material changes in estimates for the periods presented.

Stock-Based Compensation Expense

We have stock-based compensation programs, which include restricted stock units ("RSUs"); stock options and an employee stock purchase plan. We account for stock-based compensation expense, including the expense for grants of stock options and RSUs that may be settled in shares of our common stock, based on the fair values of the equity instruments issued. The fair value is determined on the measurement date, which is generally the date of grant. The fair value of our RSUs is generally measured at the market price of our common stock on the measurement date. Additionally, we use the Monte Carlo Simulation model to evaluate the derived service period and fair value of awards with market conditions, including assumptions of historical volatility, time to the next capital raise and risk-free interest rate commensurate with the vesting term. The fair value for our stock option awards is determined at the grant date using the Black-Scholes valuation model.

Assumptions for the Black-Scholes valuation model used for employee stock awards include:

- Volatility - Stock price volatility is estimated over the expected term based on a blended daily rate of industry peers stock volatility.
- Expected term - The expected term is based on a simplified method which defines the life as the weighted average of the contractual term of the options and the vesting period for each award.
- Risk-free rate - The risk-free interest rate for the expected term of the option is based on the average market rate on U.S. Treasury securities in effect during the period in which the awards were granted.
- Dividends - The dividend yield assumption is based on our history and expectation of paying no dividends in the foreseeable future.

We do not believe there is a reasonable likelihood that there will be a material change in the future estimates or assumptions we use to determine stock-based compensation expense. However, if actual results are not consistent with our estimates or assumptions, we may be exposed to changes in stock-based compensation expense that could be material or the stock-based compensation expense reported in our financial statements may not be representative of the actual economic cost of the stock-based compensation.

Accrued Legal Contingencies and Related Expenses

We follow Accounting Standards Codification ("ASC") 450, subtopic 450-20 to report accounting for loss contingencies and recoveries. Certain conditions may exist as of the date the financial statements are issued, which may result in a loss to us, but which will only be resolved when one or more future events occur or fail to occur.

We assess such contingent liabilities, and such assessment inherently involves an exercise of judgment. In assessing loss contingencies and recoveries related to legal proceedings that are pending or un-asserted claims that may result in such proceedings, we evaluate the perceived merits of any legal proceedings or un-asserted claims as well as the perceived merits of the amount of relief sought or expected to be sought therein.

If the assessment of a contingency or loss recovery indicates that it is probable that a material loss has been incurred or a loss recovery is realizable and the amount of the asset or liability can be estimated, then the estimated asset or liability would be recorded in our financial statements. If the assessment indicates that a potentially material loss contingency is not probable but is reasonably possible, or is probable but cannot be estimated, then the nature of the contingent liability, and an estimate of the range of possible losses, if determinable and material, would be disclosed. Loss contingencies considered remote are generally not disclosed unless they involve guarantees, in which case the guarantees would be disclosed.

Recently Issued and Adopted Accounting Pronouncements

See Note 2 to the accompanying consolidated financial statements for information on recently issued accounting pronouncements and recently adopted accounting pronouncements. The adoption of recently adopted accounting pronouncements did not have a material impact on our consolidated financial statements.

Results of Operations

Comparison of the years ended December 31, 2025 and 2024

Research and Development Expenses

Below is a summary of our research and development expenses during the years ended December 31, 2025 and 2024:

	Year ended December 31,			
	2025	2024	$ Change 2025 vs. 2024	% Change 2025 vs. 2024
Research and development expenses	$ 42,361,879	$ 18,701,694	$ 23,660,185	127 %

Research and development expenses for the year ended December 31, 2025 increased by $23,660,185 when compared to the year ended December 31, 2024. The increase in research and development expenses was primarily due to the following increases:

- Clinical study costs decreased by $1,497,323 due to the planning and launch of the CBeyond™ study in August of 2024, which achieved 50% enrollment by the end of 2024 and topline data in October 2025. During the first half of 2024, we also completed our Phase 2a SBI-100 trial for glaucoma which was the driver for the decrease as this program was eliminated in the first half of 2024.
- Contract manufacturing costs increased by $20,689,916 due to nimacimab drug product and drug substance runs to resupply the Phase 2a study and prepare for the Phase 2b study. Additional costs related to process intensification and dose concentration activities which are intended to allow us to seamlessly transition to a Phase 2b and build a scalable manufacturing process for future studies.
- Discovery research and development costs increased by $1,857,009 primarily from studies related to the development of a diet induced obesity model to demonstrate proof of concept and mechanism of action studies related to nimacimab.
- Quality assurance costs increased by $108,747 from the use of consultants.

- Salaries and stock-based compensation increased by $1,932,840 due to increased headcount to support our metabolic pipeline and organizational expertise.
- Consulting and advisory fees increased by $724,360 to support our nimacimab program.
- General business expenses decreased by $350,061 due to the non-recurrence of fees associated with eliminating our glaucoma program.
- Depreciation and amortization expense increased by $223,456.

General and Administrative Expenses

Below is a summary of general and administrative expenses during the years ended December 31, 2025 and 2024:

	Year ended December 31,			
	2025	2024	$ Change 2025 vs. 2024	% Change 2025 vs. 2024
General and administrative expenses	$ 15,801,686	$ 17,725,741	$ (1,924,055)	(11)%

General and administrative expenses for the year ended December 31, 2025 decreased by $1,924,055 as compared to the year ended December 31, 2024. The decrease in general and administrative expenses was primarily due to the following:

- Salaries, benefits and other direct employee related costs decreased by $742,057 primarily due to lower of stock based compensation expense in the current period due to the achievement of certain performance based milestones related to RSUs granted to members of management and members of the board of directors of the Company in 2024, the decrease was offset by increased headcount.
- Investor relations, marketing and communications expenses increased by $580,995 due primarily to a market evaluation study for nimacimab and increased investor communications and marketing activities.
- Professional, fees decreased by $1,408,506 primarily due to the decrease in professional fees from tax and financial advisory services.
- Consulting and advisory fees increased by $499,909 primarily due to the increase in finance accounting and human resource consultants and the cost of the company's annual general meeting of shareholders.
- Recruiting fees expenses decreased by $176,176 due to the one time cost to hire an executive in the prior period.
- General business expenses decreased by $314,569 primarily due to the one time Nasdaq listing fee and filing fees in the prior period and lower insurance premiums in 2025, these decreases were offset by an increase in software costs.
- Legal fees decreased by $137,852 due to decreases in litigation related activities, one-time fees related to SEC filings in the prior period, decreases in external legal costs.
- General and administrative foreign exchange expenses decreased by $244,212 due to exchange rate fluctuation of the operation of our foreign subsidiaries.

Change in Estimate for Legal Contingencies

Below is a summary of the estimated legal contingencies during the years ended December 31, 2025 and 2024:

	Year ended December 31,			
	2025	2024	$ Change 2025 vs. 2024	% Change 2025 vs. 2024
Change in estimate for legal contingencies	$ —	$ (4,234,717)	$ 4,234,717	(100)%

There was no change in estimate for legal contingency for the year ended December 31, 2025, as compared to the gain during the year ended December 31, 2024. The adjustment for the year ended December 31, 2024 was due to a change in managements estimate related to the total liability due in the Cunning Lawsuit. For additional information regarding the adjustment to the legal contingency, see Note 12 to the accompanying consolidated financial statements.

Income from Insurance Recovery

Below is a summary of the income from insurance recovery during the years ended December 31, 2025 and 2024:

	Year ended December 31,			
	2025	2024	$ Change 2025 vs. 2024	% Change 2025 vs. 2024
Income from insurance recovery	$ —	$ (2,000,000)	$ 2,000,000	(100)%

There was no income from insurance recovery for the year ended December 31, 2025, as compared to the income during the year ended December 31, 2024. The income for the year ended December 31, 2024 is due to the Company reaching a settlement with its former D&O carrier for coverage related to the Cunning Lawsuit.

Other Expense (Income)

Below is a summary of other expense (income) during the years ended December 31, 2025 and 2024:

	Year ended December 31,			
	2025	2024	$ Change 2025 vs. 2024	% Change 2025 vs. 2024
Interest expense	$ —	$ 749,308	(749,308)	(100) %
Interest income	(1,883,903)	(3,028,762)	1,144,859	(38) %
Gain from asset sale	(360,750)	(1,358,412)	997,662	(73) %
Other expense	502	2,200	(1,698)	(77) %
Total other expense (income), net	**$ (2,244,151)**	**$ (3,635,666)**	**$ 1,391,515**	**(38)%**

For the year ended December 31, 2025, we had a decrease in other income, net of $1,391,515 as compared to the same period in 2024 primarily due to:

- Gain on sale of asset decreased by $997,662, due to the one-time sale of the AVL real estate during the year ended December 31, 2024. During the year ended December 31, 2025, the Company continued to collect installment payments from the sale of VDL totaling $360,750.
- Decreased interest expense of $749,308 due to the reduction of debt.
- Decreased interest income of $1,144,859 due to the decreased interest from our cash and cash equivalents and short-term investments yields as a result of the decrease in cash equivalents and short-term investments on hand.

Liquidity, Going Concern and Capital Resources

We have incurred operating losses and negative cash flows from operations since our inception. We expect to continue to incur significant losses and negative cash flows from operations through 2026 and into the foreseeable future. We anticipate that we will continue to incur net losses in order to advance and develop potential drug candidates into preclinical and clinical development activities and support our corporate infrastructure, which includes the costs associated with being a public company. Historically, we have funded our operations primarily through issuance of equity securities, borrowings from a related party and strategic transactions.

As of December 31, 2025, had working capital of $18,888,688 and an accumulated deficit of $186,874,486. As of December 31, 2025, the Company had cash and cash equivalents in the amount of $25,737,221. For the years ended December 31, 2025 and 2024, the Company incurred losses from operations of $58,163,565 and $30,192,718, respectively. For the years ended December 31, 2025 and 2024, the Company incurred net losses of $55,924,814 and $26,567,123, respectively.

In January 2024 and March 2024, we completed the January and March PIPE Financings with institutional accredited investors, in which we raised combined net aggregate proceeds of $83,556,563.

In May 2024 we entered into the ATM Agreement under which the Company may sell up to $100,000,000 of shares of common stock through the Sales Agent. The Company has not sold any shares under the ATM Agreement as of the date hereof and is not obligated to, and cannot provide any assurances that the Company will make any sales of the shares under the ATM Agreement.

On July 1, 2024, 1,301,573 pre-funded warrants issued in the January 2024 PIPE Financing with an intrinsic value of $10,424,294, were exercised on a cashless basis, resulting in the issuance 1,301,410 shares of Company's common stock (see Note 8 to the accompanying consolidated financial statements).

On October 7, 2025, 1,059,441 pre-funded warrants issued in the January 2024 PIPE Financing with an intrinsic value of $2,012,938 were exercised on a cashless basis, resulting in the issuance of 1,059,441 shares of Company's common stock.

On December 18, 2025, 1,289,861 pre-funded warrants issued in the January 2024 PIPE Financing with an intrinsic value of $1,360,803 were exercised on a cashless basis, resulting in the issuance of 1,289,861 shares of Company's common stock.

On December 23, 2025, 25,192 pre-funded warrants issued in the January 2024 PIPE Financing with an intrinsic value of $23,177 were exercised on a cashless basis, resulting in the issuance of 25,192 shares of Company's common stock.

In August 2024, the holder of the Convertible Note exercised their conversion option and converted the principal balance of $5,000,000 into 968,973 shares of our common stock.

During the fourth quarter of 2024, we were successful in our appeal in the Ninth Circuit of the judgment of a material litigation matter, which has been remanded to the District Court for a new trial, and the bond related to the judgement was exonerated, allowing us to recover $9,000,000 in restricted cash. Additionally, in a related case with our insurance carrier, we collected $2,000,000 during the fourth quarter of 2024. The recovered funds have been reallocated to further our clinical pipeline and extend our cash runway.

Going Concern

Our independent registered public accounting firm has issued a report on our audited consolidated financial statements as of and for the year ended December 31, 2025 that included an explanatory paragraph referring to our recurring operating losses and expressing substantial doubt in our ability to continue as a going concern. Our consolidated financial statements have been prepared on a going concern basis, which assumes the realization of assets and settlement of liabilities in the normal course of business. Our consolidated financial statements do not include any adjustments to the amount and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern.

As of December 31, 2025, management estimates that we have sufficient capital to continue our operations through the fourth quarter of 2026, excluding the anticipated clinical cost of a proposed Phase 2b study and additional anticipated drug manufacturing costs to supply any such Phase 2b study. However, our continued operations beyond the fourth quarter of 2026 will depend on our ability to successfully raise additional capital through various potential sources, such as equity and/or debt financings, or strategic relationships. Our ability to access the capital markets is expected to be extremely limited. If we seek additional financing to fund our operations and there remains substantial doubt about our ability to continue as a going concern, our financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all. In addition, the uncertainty as to the resolution of the Cunning Lawsuit could limit our ability to raise new capital from investors to operate our business. If adequate funds are not available to us when needed we will be required to curtail or perhaps cease our operations which would, in turn, further raise substantial doubt about our ability to continue as a going concern. Refer to "*Risks Related to Our Limited Operating History, Financial Position and Capital Requirements — Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern, and if we are unable to continue, you may lose your entire investment*" for additional information.

Our future capital requirements will depend on many factors, including:

- the scope, rate of progress, results and costs of our clinical trials, preclinical studies and other related activities;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- the timing of, and the costs involved in, obtaining regulatory approvals for nimacimab or any future drug candidates;
- the number and characteristics of the drug candidates we seek to develop or commercialize;
- the cost of manufacturing clinical supplies, and establishing commercial supplies of our drug candidates;
- the cost of commercialization activities if our current or future drug candidates are approved for sale, including marketing, sales and distribution costs;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the amount of revenue, if any, received from commercial sales of our drug candidates, should any of our drug candidates receive marketing approval; and

- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing possible patent claims, **including litigation costs and the outcome of any such litigation.**

Cash Flows

The following is a summary of our cash flows for the periods indicated and has been derived from our consolidated financial statements which are included elsewhere in this Annual Report:

	Year ended December 31,	
	2025	**2024**
Net cash and cash equivalents provided by (used in):		
Operating activities	$ (43,062,529)	$ (25,237,480)
Investing activities	(19,500,285)	(245,615)
Financing activities	29,571	83,562,181
Net increase (decrease) in cash and cash equivalents	**$ (62,533,243)**	**$ 58,079,086**

Cash Flows from Operating Activities

The primary use of cash and cash equivalents for our operating activities during the years ended December 31, 2025 and 2024 was to fund research and development activities for our clinical product candidates, nimacimab and our prior drug candidate, SBI-100 OE, along with general and administrative activities. Our cash and cash equivalents used in operating activities also reflected changes in our working capital, net of adjustments for non-cash charges.

Cash and cash equivalents used in operating activities of $43,062,529 during the year ended December 31, 2025, reflected a net loss of $55,924,814, the loss was adjusted by aggregate non-cash charges of $8,130,296 and included a $4,731,989 decrease in our operating assets and liabilities. Non-cash charges included $723,352 of depreciation and amortization, $7,767,694 for stock-based compensation expense, $360,750 for a non-cash gain on the sale of an asset. The net change in our operating assets and liabilities included a $1,054,580 increase in our prepaid expenses and other current assets, a decrease in accounts payable of $1,395,428, and a $2,281,981 decrease in our accrued expenses and other current liabilities.

Cash and cash equivalents used in operating activities of $25,237,480 during the year ended December 31, 2024, reflected a net loss of $26,567,123, the loss was adjusted by aggregate non-cash charges of $3,958,401 and included a $2,628,758 decrease in our operating assets and liabilities. Non-cash charges included $298,640 of depreciation and amortization, $325,610 in vendor deposit write offs, $8,317,480 for stock-based compensation expense, $599,006 in non-cash interest expense from the amortization of the debt discount on our convertible debt, a gain of $4,234,717 from our change in estimate related to our legal contingency for the Cunning Lawsuit, $1,358,412 for a non-cash gain on the sale of an asset. The net change in our operating assets and liabilities included a $1,422,928 increase in our prepaid expenses and other current assets, a decrease in accounts payable of $586,533, and a $573,696 decrease in our accrued expense and other current liabilities.

Cash Flows from Investing Activities

Cash and cash equivalents used in investing activities of $19,500,285 during the year ended December 31, 2025 consisted of proceeds from the sale of VDL of $360,750 and purchase of short-term investments of $19,854,723, offset by capital expenditures from the purchase of property and equipment of $6,312.

Cash and cash equivalents used in investing activities of $245,615 during the year ended December 31, 2024 consisted of our capital expenditures from the purchase of property and equipment of $1,604,027 offset by the proceeds from the sale of the AVI building of $1,358,412.

Cash Flows from Financing Activities

During the year ended December 31, 2025, cash and cash equivalents provided by financing activities was composed of $29,571 in proceeds received from the purchase of shares of our common stock pursuant to our employee stock purchase plan.

During the year ended December 31, 2024, cash and cash equivalents provided by financing activities included $83,556,563 in net proceeds received from the January and March 2024 PIPE Financings.

Off-Balance Sheet Arrangements

There are no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

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

Not applicable.

Item 8. Financial Statements and Supplementary Data.

Our consolidated financial statements and the report of our independent registered public accounting firm are included in this report on pages F-1 through F-28.

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

Not applicable.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosures. Based upon their evaluation of those controls and procedures performed as of the end of the period covered by this report, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting as defined in Rule 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, a company's principal executive and principal financial officers and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. Generally Accepted Accounting Principles ("GAAP") and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect our transactions and dispositions of the Company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with GAAP, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the Company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, our internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, with the supervision and participation of our Chief Executive Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2025, based on criteria for effective internal control over financial reporting set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control-Integrated Framework - 2013 (COSO 2013 Framework)*.

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

As we are a smaller reporting company, our independent registered public accounting firm is not required to attest to the effectiveness of our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting during the fourth quarter ended December 31, 2025 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Director and Officer Trading Arrangements

On December 12, 2025, 5AM Partners II, LLC (the general partner of 5AM Ventures II, L.P. and 5AM Co-Investors II, L.P.) adopted a Rule 10b5-1 trading plan with Piper Sandler & Co. ("Piper Sandler"). 5AM Partners II, LLC's Rule 10b5-1 trading plan (the "10b5-1 Plan") is intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) and provides for the potential sale by Piper Sandler of up to 1,514,557 shares of the Company's common stock from the 10b5-1 Plan's effective date of January 11, 2026 until its termination date of November 16, 2026, subject to earlier termination in accordance with the terms of the 10b5-1 Plan and applicable laws, rules and regulations. Andrew Schwab is a member of the Board of Directors of the Company and a managing member of 5AM Partners II, LLC, with shared voting and investment power over the shares in the 10b5-1 Plan. Mr. Schwab disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein.

Except as set forth above, none of our directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K) during the fourth quarter of 2024.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information required by this item will be contained in our definitive Proxy Statement to be filed with the Securities and Exchange Commission on Schedule 14A in connection with our 2026 Annual General Meeting of shareholders (the "Proxy Statement"), which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2025, under the headings “Executive Officers,” “Election of Directors,” “Information Regarding the Board of Directors and Corporate Governance,” and “Delinquent Section 16(a) Reports,” and is incorporated herein by reference.

We have adopted a Code of Business Conduct and Ethics that applies to all of our directors, officers and employees, including our principal executive officer and principal financial officer. A current copy of the code is posted on the Investor Relations——Corporate Governance section of our website, which is filed with this Annual Report as Exhibit 20. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this Code of Business Conduct and Ethics by posting such information on our website, at the address and location specified above and, to the extent required by the listing standards of the Nasdaq Global Select Market, by filing a Current Report on Form 8-K with the SEC, disclosing such information.

We have adopted insider trading policies and procedures governing the purchase, sale, and other dispositions of our securities by directors, officers, and employees that are designed to promote compliance with insider trading laws, rules, and regulations, and applicable Nasdaq listing standards, as well as procedures designed to further the foregoing purposes. A copy of our insider trading policy is filed with this Annual Report as Exhibit 19.

Item 11. Executive Compensation.

The information required by this item regarding executive compensation is incorporated by reference to the information set forth in the section titled “Executive Compensation” 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” in our Proxy Statement.

The information required by Item 201(d) of Regulation S-K is incorporated by reference to the information set forth in the section titled “Executive Compensation” in our Proxy Statement.

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

The information required by this item regarding certain relationships and related transactions and director independence is incorporated by reference to the information set forth in the sections titled “Transactions with Related Parties” and “Election of Directors – Independence of the Board of Directors,” respectively, in our Proxy Statement.

Item 14. Principal Accounting 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.

Financial Statements. The following consolidated financial statements of Skye Bioscience, Inc., together with the report thereon of CBIZ CPAs P.C., an independent registered public accounting firm (PCAOB Firm No. 199) and Marcum LLP, an independent registered public accounting firm (PCAOB Firm No. 688), are included in this Annual Report.

SKYE BIOSCIENCE, INC. AND SUBSIDIARIES INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of Skye Bioscience, Inc. and Subsidiaries

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Skye Bioscience, Inc. and Subsidiaries (the "Company") as of December 31, 2025, the related consolidated statements of operations, stockholders' equity and cash flows for the year ended December 31, 2025, and the related notes (collectively referred to as the "financial statements"). In our opinion, based on our audit, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025, and the results of its operations and its cash flows for the year ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit 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 audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ CBIZ CPAs P.C.

CBIZ CPAs P.C.

We have served as the Company's auditor since 2022 (such date takes into account the acquisition of the attest business of Marcum LLP by CBIZ CPAs P.C. effective November 1, 2024).

Morristown, New Jersey
March 10, 2026

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of Skye Bioscience, Inc. and Subsidiaries

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Skye Bioscience, Inc. and Subsidiaries (the “Company”) as of December 31, 2024, the related consolidated statements of operations, stockholders’ equity (deficit) and cash flows for the year ended December 31, 2024, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit 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 audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Marcum LLP

We have served as the Company's auditor from 2022 to 2025.

Morristown, New Jersey
March 20, 2025

SKYE BIOSCIENCE, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31	
ASSETS	**2025**	**2024**
Current assets		
Cash and cash equivalents	$ 5,882,498	$ 68,415,741
Short-term investments	19,854,723	—
Prepaid expenses	504,890	201,962
Other current assets	852,036	2,209,544
Total current assets	27,094,147	70,827,247
Property and equipment, net	898,930	1,432,752
Operating lease right-of-use asset	266,646	449,864
Other assets	53,910	53,910
Total assets	$ 28,313,633	$ 72,763,773
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 2,033,431	$ 569,252
Accrued payroll liabilities	1,269,474	1,114,255
Other current liabilities	2,643,840	654,201
Estimate for accrued legal contingencies and related expenses	2,069,067	1,818,751
Operating lease liability, current portion	189,647	182,428
Total current liabilities	8,205,459	4,338,887
Non-current liabilities		
Operating lease liability, net of current portion	83,999	273,162
Total liabilities	8,289,458	4,612,049
Commitments and contingencies (Note 12)		
Stockholders' equity		
Preferred stock, $0.001 par value; 200,000 shares authorized at December 31, 2025 and 2024; no shares issued and outstanding at December 31, 2025 and 2024	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2025 and 2024, respectively; 33,378,139 and 30,974,559 shares issued and outstanding at December 31, 2025 and 2024, respectively	33,379	30,975
Additional paid-in-capital	206,865,282	199,070,421
Accumulated deficit	(186,874,486)	(130,949,672)
Total stockholders' equity	20,024,175	68,151,724
Total liabilities and stockholders' equity	$ 28,313,633	$ 72,763,773

See accompanying notes to the consolidated financial statements.

SKYE BIOSCIENCE, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31	
	2025	**2024**
Operating expenses		
Research and development	$ 42,361,879	$ 18,701,694
General and administrative	15,801,686	17,725,741
Change in estimate for legal contingency	—	(4,234,717)
Income from insurance recovery	—	(2,000,000)
Total operating expenses	58,163,565	30,192,718
Operating loss	(58,163,565)	(30,192,718)
Other (income) expense		
Interest expense	—	749,308
Interest income	(1,883,903)	(3,028,762)
Gain from asset sale	(360,750)	(1,358,412)
Other expense	502	2,200
Total other (income) expense, net	(2,244,151)	(3,635,666)
Loss before income taxes	(55,919,414)	(26,557,052)
Provision for income taxes	5,400	10,071
Net loss	$ (55,924,814)	$ (26,567,123)
Loss per common share		
Basic	$ (1.41)	$ (0.73)
Diluted	$ (1.41)	$ (0.73)
Weighted average shares of common stock outstanding used to compute loss per share:		
Basic	39,662,664	36,486,519
Diluted	39,662,664	36,486,519

See accompanying notes to the consolidated financial statements.

SKYE BIOSCIENCE, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (55,924,814)	$ (26,567,123)
Adjustments to reconcile net loss to net cash, cash equivalents used in operating activities:		
Write-down of vendor deposits	—	325,610
Depreciation and amortization	723,352	298,640
Net loss on disposal of asset	—	10,794
Stock-based compensation expense	7,767,694	8,317,480
Amortization of debt discount	—	599,006
Change in estimate for legal contingencies	—	(4,234,717)
Gains from asset sales	(360,750)	(1,358,412)
Changes in assets and liabilities:		
Prepaid expenses	(302,928)	(7,703)
Other current assets	1,357,508	(1,415,225)
Other assets	—	(45,601)
Accounts payable	1,395,428	(586,533)
Accrued interest – related party	—	(126,027)
Accrued interest – legal contingency	—	(234,750)
Accrued payroll liabilities	155,219	225,874
Other current liabilities	2,308,706	(344,351)
Operating lease liability	(181,944)	(94,442)
Net cash, cash equivalents used in operating activities	(43,062,529)	(25,237,480)
Cash flows from investing activities:		
Proceeds from asset sales, net of legal expenses	360,750	1,358,412
Purchase of short-term investment	(19,854,723)	—
Purchases of property and equipment	(6,312)	(1,604,027)
Net cash, and cash equivalents used in investing activities	(19,500,285)	(245,615)
Cash flows from financing activities:		
Proceeds from PIPE financing, net of $6,434,447 of issuance costs	—	83,556,563
Purchase under employee stock purchase plan	29,571	—
Proceeds from option exercises	—	5,618
Net cash, and cash equivalents provided by financing activities	29,571	83,562,181
Net increase in cash and cash equivalents	(62,533,243)	58,079,086
Cash, cash equivalents, beginning of year	$ 68,415,741	$ 10,336,655
Cash, cash equivalents, end of year	$ 5,882,498	$ 68,415,741
Cash paid during the year for:		
Interest	$ —	$ 433,336
Income taxes	5,400	5,200
Supplemental disclosures of non-cash financing activities:		
Right of use asset obtained in exchange for operating lease liabilities	$ —	$ 306,764
Conversion of convertible note - related party	—	4,971,004

See accompanying notes to the consolidated financial statements.

SKYE BIOSCIENCE, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' (DEFICIT) EQUITY

	Stockholders' Deficit				
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amounts			
Balance, December 31, 2023	**12,349,243**	**$ 12,349**	**$ 102,238,382**	**$ (104,382,549)**	**$ (2,131,818)**
Issuance of Common Stock and Warrants, net of equity issuance costs $6,434,447	15,713,664	15,714	83,540,849	—	83,556,563
Stock-based compensation expense	639,664	640	8,316,840	—	8,317,480
Exercise of stock options	1,605	2	5,616	—	5,618
Exercise of pre-funded warrants	1,301,410	1,301	(1,301)	—	—
Conversion of convertible note - related Party	968,973	969	4,970,035	—	4,971,004
Net loss for the year ended December 31, 2024	—	—	—	(26,567,123)	(26,567,123)
Balance, December 31, 2024	**30,974,559**	**$ 30,975**	**$ 199,070,421**	**$ (130,949,672)**	**$ 68,151,724**
Stock-based compensation expense	10,625	11	7,767,683	—	7,767,694
Purchases under employee stock purchase plan	18,461	18	29,553	—	29,571
Exercise of pre-funded warrants	2,374,494	2,375	(2,375)	—	—
Net loss for the year ended December 31, 2025	—	—	—	(55,924,814)	(55,924,814)
Balance, December 31, 2025	**33,378,139**	**$ 33,379**	**$ 206,865,282**	**$ (186,874,486)**	**$ 20,024,175**

See accompanying notes to the consolidated financial statements.

1. Nature of Operations and Business Activities

Nature of Operations

Skye Bioscience, Inc. (the “Company” or “Skye”) was incorporated in Nevada on March 16, 2011. The Company is a clinical stage biotechnology company developing next-generation molecules that modulate G-protein-coupled receptors ("GPCRs") to treat obesity, overweight, and related conditions.

As of December 31, 2025, the Company has devoted substantially all its efforts to securing its product pipeline, carrying out its own research and development, preparing for and conducting clinical trials, building infrastructure and raising capital. The Company has not yet realized revenue from its planned principal operations and is a number of years away from potentially being able to do so.

Liquidity and Going Concern

The Company has incurred operating losses and negative cash flows from operations since inception and as of December 31, 2025, had a working capital of $18,888,688 and an accumulated deficit of 186,874,486. As of December 31, 2025, the Company had unrestricted cash, cash equivalents and short-term investments in the amount of $25,737,221. For the years ended December 31, 2025 and 2024, the Company incurred losses from operations of $58,163,565 and $30,192,718, respectively. For the years ended December 31, 2025 and 2024, the Company incurred net losses of $55,924,814 and $26,567,123, respectively. The Company expects to continue to incur significant losses and negative cash flows from operations through 2026 and expects to incur significant losses and negative cash flows from operations in the future.

The Company’s continued existence is dependent on its ability to raise sufficient additional funding to cover operating expenses and to carry out its research and development activities. As the Company is continuing its clinical trials, it has increased research and development spending and increased cash used in operating activities. This factor, among others, has resulted in an overall increase in cash used in operating activities for the year ended December 31, 2025. As of the date that these financials are filed, management estimates that the Company has sufficient capital to continue its operations through the fourth quarter of 2026, excluding the anticipated clinical cost of a proposed Phase 2b study and additional anticipated drug manufacturing costs to supply any such Phase 2b study. However, the Company's continued operations beyond the fourth quarter of 2026 will depend on its ability to successfully raise additional capital through various potential sources, such as equity and/or debt financings, or strategic relationships. If adequate funds are not available to the Company when needed it will be required to curtail or perhaps cease operations which would, in turn, further raise substantial doubt about its ability to continue as a going concern. These conditions give rise to substantial doubt as to the Company’s ability to continue as a going concern within one year after the date that these financial statements are issued.

It is possible that the Company may encounter issues relating to supply chain issues, a lack of production or laboratory resources, global economic and political conditions, pandemics or cyberattacks that could cause business disruptions and clinical trial delays which will need to be managed in the future. The factors to take into account in going concern judgments and financial projections include travel bans, restrictions, government assistance and potential sources of replacement financing, financial health of service providers and the general economy. In addition, increased inflation has had, and may continue to have, an effect on interest rates. Increased interest rates may adversely affect the terms under which the Company can obtain, any potential additional funding.

After considering the plans to alleviate substantial doubt, management has concluded that there is substantial doubt about the Company’s ability to continue as a going concern within one year after the date that these financial statements are issued. The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

2. Summary of Significant Accounting Policies

Basis of Presentation

The preparation of financial statements in conformity with U.S. Generally Accepted Accounting Principles ("GAAP") requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and the accompanying notes. Actual results could differ from those estimates.

Certain reclassifications have been made to the amounts in prior periods to conform to the current period's presentation, including reclassifying discovery research and development expense amounts from external clinical development expenses into other research and development expenses, as described in Note 13, Segment Reporting. Such reclassifications did not have a material impact on the accompanying unaudited condensed consolidated financial statements.

Principles of Consolidation

The accompanying consolidated financial statements as of December 31, 2025, include the accounts of the Company and its wholly owned subsidiaries SKYE Bioscience Australia, EHT, BRB and Nemus Sub. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of income and expense during the reporting period. Actual results could differ from those estimates. The most significant accounting estimates inherent in the preparation of the Company's financial statements include estimates and judgements used in determining stock based compensation expense, estimated legal contingencies and estimates related to the vendors' percentage of completion under its research and development contracts, which are not readily apparent from other sources.

Risks and Uncertainties

The Company's operations are subject to a number of risks and uncertainties, including but not limited to, changes in the general economy, the size and growth of the potential market for the Company's product candidates, uncertainties related to the current global environment, including economic factors such as inflation, and risks related to the global supply chain disruptions (Note 1), risks related to operating in a virtual environment, results of research and development activities, uncertainties surrounding regulatory developments in the United States, Canada, the European Union, and Australia and the Company's ability to attract new funding.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. The carrying values of those investments approximate their fair value due to their short maturity and liquidity. Cash and cash equivalents includes cash on hand and amounts on deposit with financial institutions, which amounts may at times exceed federally insured limits. The Company has not experienced any losses on such accounts and does not believe it is exposed to any significant credit risk.

Property and Equipment, net

Property and equipment is stated at cost less accumulated depreciation and amortization. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, generally three to five years. Leasehold improvements are amortized over the shorter of the estimated useful life of the improvements or the remaining lease term. Expenditures for repairs and maintenance, which do not extend the useful life of the property and equipment, are expensed as incurred. Upon retirement, the asset cost and related accumulated depreciation are relieved from the accompanying Consolidated Balance Sheets.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (the "exit price") in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. A fair value hierarchy based on three levels of inputs, of which the first two are considered observable, and the last is considered unobservable, is used to measure fair value:

Level 1: Valuations for assets and liabilities traded in active markets from readily available pricing sources such as quoted prices in active markets for identical assets or liabilities.

Level 2: Observable inputs (other than Level 1 quoted prices) such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The carrying values of the Company's financial instruments approximate their fair value due to their short maturities.

Income Taxes

The Company accounts for deferred income tax assets and liabilities based on differences between the financial reporting and tax bases of assets and liabilities, net operating loss carryforwards (the "NOLs") and other tax credit carryforwards. These items are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in the period that includes the enactment date. Any interest or penalties would be recorded in the Company's Consolidated Statements of Operations in the period incurred. When necessary, the Company recognizes interest and penalties related to income tax matters in income tax expense.

The Company records a valuation allowance against deferred tax assets to the extent that it is more likely than not that some portion or all of the deferred tax assets will not be realized. In making such determinations, management considers all available positive and negative evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax planning strategies and recent financial operations. Due to the substantial doubt related to the Company's ability to utilize its deferred tax assets, a valuation allowance for the full amount of the deferred tax assets has been established at December 31, 2025 and 2024. As a result of this valuation allowance, there are no income tax benefits reflected in the accompanying Consolidated Statements of Operations to offset pre-tax losses.

The Company recognizes a tax benefit from uncertain tax positions when it is more likely than not (50%) that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits of the position.

Warrants Issued in Connection with Financings

The Company generally accounts for warrants issued in connection with debt and equity financings as a component of equity, unless the warrants include a conditional obligation to issue a variable number of shares or there is a deemed possibility that the Company may need to settle the warrants in cash. For warrants issued with a conditional obligation to issue a variable number of shares or the deemed possibility of a cash settlement, the Company records the fair value of the warrants as a liability at each balance sheet date and records changes in fair value in other expense, net in the Consolidated Statements of Operations.

Research and Development Expenses and Licensed Technology

Research and development costs are expensed when incurred. These costs may consist of external research and development expenses incurred under agreements with third party contract research organizations and investigative sites; third party manufacturing organizations and consultants; license fees; employee-related expenses, which include salaries and benefits for the personnel involved in the Company's preclinical; and clinical drug development activities, other expenses and equipment and laboratory supplies.

Costs incurred for the rights to use licensed technologies in the research and development process, including licensing fees and milestone payments, are charged to research and development expense as incurred in situations where the Company has not identified an alternative future use for the acquired rights, and are capitalized in situations where there is an identified alternative future use. None of the costs associated with the use of licensed technologies has been capitalized to date.

Stock-Based Compensation Expense

Stock-based compensation expense is estimated at the grant date based on the fair value of the award, and the fair value is recognized as expense ratably over the vesting period with forfeitures accounted for as they occur.

Upon the exercise of stock option awards, the Company's policy is to issue new shares of its common stock. The Company uses the Black-Scholes valuation method for estimating the grant date fair value of stock options using the following assumptions:

- Volatility - Stock price volatility is estimated over the expected term based on a blended daily rate of industry peers stock volatility.
- Expected term - The expected term is based on a simplified method which defines the life as the weighted average of the contractual term of the options and the vesting period for each award.
- Risk-free rate - The risk-free interest rate for the expected term of the option is based on the average market rate on U.S. Treasury securities in effect during the period in which the awards were granted.

- Dividends - The dividend yield assumption is based on the Company's history and expectation of paying no dividends in the foreseeable future.

Additionally, the Company uses the Monte Carlo Simulation model to evaluate the derived service period and fair value of awards with market conditions, including assumptions of historical volatility and risk-free interest rate commensurate with the vesting term.

Loss Per Common Share

The Company applies ASC No. 260, *Earnings per Share* in calculating its basic and diluted loss per common share. Basic loss per common share is computed by dividing net loss available to common stockholders by the weighted-average number of shares of common stock outstanding for the period. Diluted loss per share of common stock is computed by giving effect to all potential common stock equivalents outstanding for the period determined using the treasury stock method. For purposes of this calculation, options to purchase common stock, restricted stock units and warrants to purchase common stock are considered to be common stock equivalents. In periods with a reported net loss, such common stock equivalents are excluded from the calculation of diluted net loss per share of common stock if their effect is anti-dilutive. For additional information regarding the loss per share (see Note 10).

Leases

The Company applies ASU, No. 2016-02, *Leases (Topic 842),* in accounting for operating lease arrangements.

At the inception of an arrangement, the Company determines whether the arrangement is, or contains, a lease based on the unique facts and circumstances present. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in the lease contract is typically not readily determinable. As such, the Company utilizes its incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received.

Lease expense is recognized over the expected term on a straight-line basis. Operating leases are recognized on the Consolidated Balance Sheets as operating lease right-of-use assets, operating lease liability, current portion and operating lease liability, net of current portion.

Government Assistance

The Company adopted ASU 2021-10 *Government Assistance* on January 1, 2022. The Company accounts for the tax rebates received from the Australian Taxation Office ("ATO") under such guidance. The Company accounts for the rebates that it receives under the AusIndustry research and development tax incentive program under the income recognition model of IAS 20. Under this model, when there is reasonable assurance that the rebate will be received, the Company recognizes the income from the tax rebate as an offset to research and development expense during the period which the benefit applies to the research and development costs incurred. The total tax rebates received under the AusIndustry incentive program were $0 for the year ended December 31, 2025 related to incentives earned in the prior year and $493,362 for the year ended December 31, 2024.

Foreign Currency Translation

The Company's reporting currency and the functional currency of its foreign subsidiaries is the United States dollar. The local currencies of its foreign subsidiaries are the Canadian Dollar ("CAD") and Australian dollar ("AUD"). Assets and liabilities are remeasured based on the exchange rates at the balance sheet date 0.7305 for the CAD, 0.6703 for the AUD as of December 31, 2025 and 0.6952 for the CAD and 0.623 for the AUD as of December 31, 2024, while expense accounts are remeasured at the weighted average exchange rate for the period 0.7249 for the CAD and 0.6645 for the AUD for the year ended December 31, 2025 and 0.7023 for the CAD and 0.6342 for the AUD as of December 31, 2024. Equity accounts are remeasured at historical exchange rates. The resulting remeasurement adjustments are recognized in general and administrative expenses in the consolidated financial statements.

During the years ended December 31, 2025 and 2024, the Company recorded foreign currency remeasurement gain of $96,190 and a loss of $148,023, respectively, which are reflected in general and administrative expenses in the accompanying Consolidated Statements of Operations.

Foreign currency gains and losses resulting from transactions denominated in foreign currencies are recorded in the Consolidated Statements of Operations. During the years ended December 31, 2025 and 2024, the Company recorded foreign currency transaction loss of $1,085,098 and gain of $49,984, respectively, which is reflected in the loss from operations in the accompanying consolidated statement of operations.

Commitments and Contingencies

The Company follows ASC 440, *Commitments* and ASC 450, *Contingencies*, subtopic 450-20 to report accounting for contingencies and commitments respectively. Certain conditions may exist as of the date the financial statements are issued, which may result in a loss to the Company, but which will only be resolved when one or more future events occur or fail to occur.

The Company assesses such contingent liabilities, and such assessment inherently involves an exercise of judgment. In assessing loss contingencies related to legal proceedings that are pending against the Company or un-asserted claims that may result in such proceedings, the Company evaluates the perceived merits of any legal proceedings or un-asserted claims as well as the perceived merits of the amount of relief sought or expected to be sought therein.

If the assessment of a contingency indicates that it is probable that a material loss has been incurred and the amount of the liability can be estimated, then the estimated liability would be accrued in the Company's financial statements. If the assessment indicates that a potentially material loss contingency is not probable but is reasonably possible, or is probable but cannot be estimated, then the nature of the contingent liability, and an estimate of the range of possible losses, if determinable and material, would be disclosed. Loss contingencies considered remote are generally not disclosed unless they involve guarantees, in which case the guarantees would be disclosed. Refer to Note 12 for additional information.

In accordance with ASC 450, Contingencies, subtopic 450-20, the Company does not reflect a contingency that may result in a gain until it is realized.

Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board ("FASB") issued ASU 2023-07, S*egment Reporting (Topic 280)*: *Improvements to Reportable Segment Disclosures*. The amendments in this ASU require disclosures, on an annual and interim basis, of significant segment expenses that are regularly provided to the chief operating decision maker ("CODM"), as well as the aggregate amount of other segment items included in the reported measure of segment profit or loss. This ASU requires that a public entity disclose the title and position of the CODM and an explanation of how the CODM uses the reported measure(s) of segment profit or loss in assessing segment performance and deciding how to allocate resources. This ASU is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years, with early adoption permitted. The amendments in this ASU should be applied retrospectively to all prior periods presented in the financial statements. The Company adopted the ASU and determined that its adoption did not have a material impact on the Company's consolidated financial statements and related disclosures. As defined in the ASU, operating segments are components of an enterprise about which discrete financial information is regularly provided to the CODM in making decisions on how to allocate resources and assess performance for the organization. The Company operates and manages its business as one reportable and operating segment — pharmaceutical development. The Company's CODM is the Chief Executive Officer. The Company's CODM reviews consolidated operating results to make decisions about allocating resources and assessing performance for the entire Company. See Segment Note 13.

In December 2023, the FASB issued Accounting Standards Update ("ASU") 2023-09, Improvements to Income Tax Disclosures. This ASU requires greater disaggregation of information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. This ASU applies to all entities subject to income taxes and is intended to help investors better understand an entity's exposure to potential changes in jurisdictional tax legislation and assess income tax information that affects cash flow forecasts and capital allocation decisions. This ASU is effective for annual periods beginning after December 15, 2024, with early adoption permitted. This ASU should be applied on a prospective basis although retrospective application is permitted. The Company adopted this ASU as of January 1, 2025, and the related disclosure, a tabular reconciliation of the provision for income taxes to the amount computed, is described in Note 11.

Recent Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued Accounting Standards Update ("ASU") 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which requires additional disclosure of the nature of expenses included in the income statement. The standard requires disclosures about specific types of expenses included in the expense captions presented in the income statement as well as disclosures about selling expenses. This ASU is effective for fiscal years beginning after December 15, 2026, and interim periods beginning after December 15, 2027, with early adoption permitted. The requirements should be applied on a prospective basis while retrospective application is permitted. The Company is currently evaluating the impact the adoption of this ASU will have on its consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-11 – Interim Reporting (“ASU 2025-11”) which is intended to improve the navigability of the guidance in ASC 270, Interim Reporting, and clarify when it applies. Under the amendments, an entity is subject to ASC 270 if it provides interim financial statements and notes in accordance with GAAP. ASU 2025-11 also addresses the form and content of such financial statements, interim disclosures requirements, and establishes a principle under which an entity must disclose events since the end of the last annual reporting period that have a material impact on the entity. ASU 2025-11 is effective for interim reporting periods within annual reporting periods beginning after December 15, 2027, and early adoption is permitted. The Company is currently evaluating the impact the adoption of ASU 2025-11 may have on the Company’s consolidated financial statements and disclosures.

In December 2025, the FASB issued its final Accounting Standard Update ("ASU") which makes improvements to the Accounting Standards Codification ("ASC") in response to feedback from stakeholders. This standard, issued as ASU 2025-12, specifically updates the ASC for a broad range of topics arising from technical corrections, unintended application of the ASC, clarifications, and other minor improvements. This update is effective for annual reporting periods beginning after December 15, 2026, including interim reporting periods within those annual reporting periods. The Company is currently evaluating the effect of this guidance on its financial statements and related disclosures.

3. Fair Value Measurement

The following table sets forth the Company’s financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy:

	Fair Value Measurement as of December 31, 2025		
	Valuation Hierarchy		Total
Assets:			
Money market funds (included in cash and cash equivalents)	Level 1	$	1,461,609
U.S. treasury obligations (included in short-term investments)	Level 1		19,854,723
Total cash equivalents and marketable securities		**$**	**21,316,332**

4. Assets Acquisitions and Dispositions

Acquisition of Emerald Health Therapeutics, Inc.

On May 11, 2022, the Company entered into an Arrangement Agreement, as amended on June 14, 2022, July 15, 2022 and October 14, 2022 (the “Arrangement Agreement”) with Emerald Health Therapeutics, Inc., a corporation existing under the laws of the Province of British Columbia, Canada (“EHT”), pursuant to a plan of arrangement under the Business Corporations Act (British Columbia) (the “EHT Acquisition”).
At the time of the EHT Acquisition there were arrangements in place to sell the acquired assets and liabilities that comprised two of EHT's subsidiaries, Emerald Health Therapeutics Canada, Inc. ("EHTC") and VDL. As of December 31, 2024 the Company has divested both of EHT's former operating entities, and the divestiture of substantially all of EHT's assets, including the real estate held by AVI.

Sale of real estate

The wind down of EHT's operations included the disposition of real estate held by AVI (the "AVI building"). At the time of the Company’s acquisition of EHT on November 10, 2022 (the “EHT Acquisition”), none of the purchase consideration was allocated to the fair value of the AVI building. As a result of the sale of the AVI building, for the year ended December 31, 2024, the Company recorded a gain of $1,145,141 as a Gain from Asset Sales within the Other Income and Expense section of the Company's Consolidated Statements of Operations.

Divestiture of VDL, Release and Discharge Agreement

On July 17, 2024, the Company entered into a transaction, release and discharge agreement with the purchaser of Verdelite Sciences, Inc. ("VDL"). Under the transaction, release and discharge agreement, the purchase price of VDL was adjusted in exchange for a full release of any future claims by VDL against the Company. As part of the agreement, the parties agreed to a reduced installment payment schedule for the remaining aggregate balance of the purchase price of $2,047,080 through December 2027. The remainder of the purchase price receivable bears interest at 8%. Upon signing the transaction, release and discharge agreement, the Company recorded $360,750 and $213,404 as a Gain from Asset Sales within the Other Income and

Expense section of the Company's Consolidated Statement of Operations for twelve months ended December 31, 2025 and 2024, respectively.

5. Prepaid Expenses, Other Current Assets, Property and Equipment and Other Current Liabilities

Prepaid expenses consist of the following:

	As of December 31	
	2025	**2024**
Prepaid clinical expenses	$ 231,493	$ 13,078
Total other prepaid expenses	273,397	188,884
	$ 504,890	**$ 201,962**

Other current assets consist of the following:

	As of December 31	
	2025	**2024**
Vendor deposits	827,781	1,997,274
Other tax receivables	10,474	5,065
Other current assets	13,781	207,205
	$ 852,036	**$ 2,209,544**

Property and equipment, net consists of the following:

	As of December 31	
	2025	**2024**
Machinery and equipment	$ 1,527,419	$ 1,527,419
Furniture and fixtures	24,496	18,184
Computer equipment	96,744	96,744
Leasehold improvements	23,918	23,918
Total property and equipment, gross	1,672,577	1,666,265
Less: accumulated depreciation and amortization	(773,647)	(233,513)
Total property and equipment, net	**$ 898,930**	**$ 1,432,752**

Depreciation and amortization expense for the twelve months ended December 31, 2025 and twelve months ended December 31, 2024 was $540,135 and $203,757, respectively.

Other current liabilities consist of the following:

	As of December 31	
	2025	**2024**
Research and development costs	$ 2,518,724	$ 325,415
Legal expenses	88,838	114,359
Consulting and professional fees	26,356	109,375
Other accrued liabilities	9,922	105,052
	$ 2,643,840	**$ 654,201**

6. Warrants

There are significant judgements and estimates inherent in the determination of the fair value of the Company’s warrants. These judgements and estimates include assumptions regarding the Company’s future operating performance and the determination of the appropriate valuation methods. If the Company had made different assumptions, the fair value of the warrants could have been significantly different (See Note 2).

Warrants

Warrants vested and outstanding as of December 31, 2025 are summarized as follows:

Source	Exercise Price	Remaining Term (Years)	Number of Warrants Outstanding
2016 Common Stock Warrants to Service Providers	287.50	0.83	160
2021 Inducement Warrants	37.50	0.57	84,667
2021 Inducement Warrants to Placement Agent	47.00	0.57	5,927
2021 Common Stock Warrants	22.50	0.74	311,113
2021 Common Stock Warrants to Placement Agent	27.50	0.74	21,778
August 2023 Convertible Note Common Stock Warrants	5.16	7.63	340,000
August 2023 PIPE Financing Common Stock Warrants	5.16	7.63	2,325,537
January 2024 Pre-Funded Warrants Common Stock	0.001	Indefinite	6,300,860
Total warrants outstanding as of December 31, 2025			**9,390,042**

As of December 31, 2025, all of the Company's warrants are fully vested.

January 2024 Pre-Funded Warrants

In connection with the January 2024 PIPE Financing (as defined in Note 8), the Company issued the Pre-Funded Warrants. The Pre-Funded Warrants have an exercise price of $0.001 per share, and were exercisable immediately upon issuance until exercised in full. The gross proceeds from the issuance of these Pre-Funded Warrants was $22,991,015. The Company determined that the Pre-Funded Warrants are freestanding instruments that do not meet the definition of a liability or derivative. The Pre-Funded Warrants are indexed to the Company’s common stock and meet all other conditions for equity classification. Accordingly, the Pre-Funded Warrants are classified as equity and are accounted for as a component of additional paid-in capital at the time issued. The Company also determined that the Pre-Funded Warrants should be included in the determination of basic and diluted earnings per share.

7. Debt

Convertible Note - Related Party

On August 15, 2023, the Company entered into a Secured Note and Warrant Purchase Agreement with MFDI, LLC (“MFDI”), pursuant to which the Company issued to MFDI a $5,000,000 secured convertible promissory note (the "Convertible Note") and a warrant to purchase 340,000 shares of common stock on August 18, 2023 . The Convertible Note accrued interest at a rate of 10% per annum and had a fixed conversion price at $5.16.

On August 8, 2024, MFDI exercised the conversion option under the Convertible Note and converted the full principal balance. This conversion resulted in the issuance of 968,973 shares of the Company's common stock and the payment of accrued interest in cash.

In the original accounting for the Convertible Note, the Company allocated $4,068,424 in proceeds to the debt host and $931,576 in proceeds to the freestanding warrants based on relative fair value. The debt discounts of $931,576 and $26,316 related to the warrants, and debt issuance costs, respectively, were amortized over the term of the Convertible Note using the effective interest rate method. Amortization of the debt discount was recognized as non-cash interest expense in Other expense within the Consolidated Statements of Operations.

Accrued interest on the Convertible Note was payable quarterly within 30 days of the last day of each calendar quarter. The debt discounts related to the warrants, and debt issuance costs, were amortized over the term of the Convertible Note using the effective interest rate method. Amortization of the debt discount is recognized as non-cash interest expense in Other (income) expense within the Consolidated Statements of Operations. Through the date of conversion, the Convertible Note is classified as Level 2 of the fair value hierarchy model based on market prices that can be corroborated with observable market data for the Company's common stock.

For the year ended December 31, 2024, the effective interest rate on the Convertible Note was 31.39%.

Interest Expense

There was no interest expense in 2025. The Company's interest expense for 2024 consists of the following:

	Year Ended December 31, 2024
Related party interest expense – stated rate	$ 302,740
Legal judgment estimated interest (income) expense	(234,750)
Bond premium	59,929
Premium on irrevocable letter of credit	22,383
Non-cash interest expense:	
Amortization of debt discount	582,550
Amortization of transaction costs	16,456
	$ 749,308

8. Stockholders' Equity and Capitalization

The Company reserved shares of common stock, on an as-if converted basis, for issuance as follows:

	Year Ended December 31,	
	2025	**2024**
Options issued and outstanding	4,528,555	3,036,603
Shares available for issuance under the Amended and Restated Omnibus Incentive Plan	319,822	119,046
Shares available for issuance under ESPP	328,427	192,016
Shares available for issuance under our Inducement Plan	142,500	286,500
Restricted stock units issued and outstanding	492,488	503,113
Warrants issued and outstanding	9,390,042	11,880,110
	15,201,834	**16,017,388**

PIPE Financings

January 2024 PIPE Financing

On January 29, 2024, the Company entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which on January 31, 2024, the Company issued an aggregate of 11,713,664 shares of common stock and 9,978,739 pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 9,978,739 shares of common stock (the "January 2024 PIPE Financing") for an aggregate purchase price of $49,991,010. The January 2024 PIPE Financing was priced at $2.31 per common share and $2.30 per Pre-Funded Warrant based on the 5-day average share price preceding January 29, 2024. The Pre-Funded Warrants are exercisable at any time for an exercise price of $0.001.

In connection with the January 2024 PIPE Financing, the Company incurred $3,823,752 in direct equity issuance costs for net proceeds of $46,167,258.

March 2024 PIPE Financing

On March 11, 2024, the Company entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which on March 13, 2024, the Company issued an aggregate of 4,000,000 shares of common stock (the "March 2024 PIPE Financing") for an aggregate purchase price of $40,000,000. The March 2024 PIPE Financing was priced at $10.00 per common share.

In connection with the March 2024 PIPE Financing, the Company incurred $2,610,695 in direct equity issuance costs for net proceeds of approximately $37,389,305.

Convertible Note - Related Party

On August 8, 2024, MFDI exercised the conversion option under the Convertible Note and converted the full principal balance. This conversion resulted in the issuance of 968,973 shares of the Company's common stock and the payment of accrued interest in cash.

Stock Issued for Services

For the twelve months ended December 31, 2025 and 2024, the Company released 0 and 5,000 shares, respectively, of common stock to a service provider (Note 9).

Warrant Exercises

Prefunded Warrant Exercise

On July 1, 2024, 1,301,573 pre-funded warrants issued in the January 2024 PIPE Financing with an intrinsic value of $10,424,294 were exercised on a cashless basis, resulting in the issuance of 1,301,410 shares of Company's common stock.

On October 7, 2025, 1,059,441 pre-funded warrants issued in the January 2024 PIPE Financing with an intrinsic value of $2,012,938 were exercised on a cashless basis, resulting in the issuance of 1,059,441 shares of Company's common stock.

On December 18, 2025, 1,289,861 pre-funded warrants issued in the January 2024 PIPE Financing with an intrinsic value of $1,360,803 were exercised on a cashless basis, resulting in the issuance of 1,289,861 shares of Company's common stock.

On December 23, 2025, 25,192 pre-funded warrants issued in the January 2024 PIPE Financing with an intrinsic value of $23,177 were exercised on a cashless basis, resulting in the issuance of 25,192 shares of Company's common stock.

Restricted Stock Units Released

A total of 10,625 and 634,664 RSUs were vested and settled in 2025 and 2024, respectively

9. Stock-Based Compensation

Stock Incentive Plan

On October 31, 2014, the Board approved the Company's 2014 Omnibus Incentive Plan (the "2014 Plan"). The 2014 Plan authorizes the issuance of awards including stock options, stock appreciation rights, restricted stock, stock units and performance units to employees, directors, and consultants of the Company. On June 14, 2022, the Board approved the 2014 Amended and Restated Omnibus Incentive Plan (the "2014 Amended and Restated Plan") which replaced the 2014 Plan in its entirety. On September 29, 2023, the Board and Majority Stockholders adopted and approved Amendment No. 1 to the 2014 Amended and Restated Plan. Amendment No. 1 to the 2014 Amended and Restated Plan became effective on November 6, 2023. On October 22, 2024, the second amendment and restatement of the Company's 2014 Amended and Restated Plan was approved to increase the number of shares of the Company's common stock issuable thereunder by 1,535,655 to increase the number of incentive stock options that may be granted thereunder to 4,000,000, extend the expiration date of the plan to September 10, 2034, update the name of the plan to the "Skye Bioscience, Inc. Amended and Restated Omnibus Incentive Plan" and make certain administrative amendments (as so amended and restated, the "Amended and Restated Plan").

The Amended and Restated Plan, among other things, provides that each January 1 beginning in 2023 and ending on (and including) January 1, 2032 the number of shares will increase by 5% of the outstanding shares of common stock as of the prior December 31, unless the Board of Directors of the Company decides to a lesser increase.

As of December 31, 2025, the shares available for future grant under the Amended and Restated Plan are as follows:

	Shares Available for Grant
Available as of December 31, 2024	**119,046**
Share pool increase	1,548,728
Forfeited/Cancelled	324,248
Option grants	(1,672,200)
Available as of December 31, 2025	**319,822**

2024 Inducement Equity Incentive Plan

On July 2, 2024, the Board adopted the Skye Bioscience, Inc. 2024 Inducement Equity Incentive Plan (as amended and restated, the "Inducement Plan"). The Inducement Plan was adopted in order to grant share-based awards to newly hired employees as an inducement to join the Company. The terms of the Inducement Plan are substantially similar to the terms of the Company's 2014 Amended and Restated Plan with the exception that awards may only be made to an employee who has not previously been an employee or member of the Board of Directors of the Company if the award is in connection with commencement of employment. The Company has reserved 600,000 shares of the Company's common stock for issuance pursuant to awards granted under the Inducement Plan.

As of December 31, 2025, the shares available for future grant under the Amended and Restated Plan are as follows:

	Shares Available for Grant
Available as of December 31, 2024	**286,500**
Forfeited/Cancelled	31,000
Option grants	(175,000)
Available as of December 31, 2025	**142,500**

Stock Options

Options granted under the Company's equity incentive plans expire no later than ten years from the date of grant. Options granted under the Company's equity incentive plans may be either incentive or non-qualified stock options. For incentive and non-qualified stock option grants, the option price shall be at least 100% of the fair value on the date of grants, as determined by the Company's Board of Directors. If at any time the Company grants an option, and the optionee directly or by attribution owns stock possessing more than 10% of the total combined voting power of all classes of stock of the Company, the option price shall be at least 110% of the fair value and shall not be exercisable more than five years after the date of grant. The shares issued generally vest over a period of one to four years from the date of grant.

The following is a summary of option activities under the Company's Amended and Restated Plan and the Inducement Plan for the year ended December 31, 2025:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value*
Outstanding, December 31, 2024	**3,036,603**	**$ 7.72**	**8.91**	**$ 22,624**
Granted	1,847,200	2.85		
Forfeited	(176,334)	4.34		
Cancelled	(178,914)	10.99		
Outstanding, December 31, 2025	**4,528,555**	**$ 5.74**	**8.73**	**$ —**
Exercisable, December 31, 2025	**1,863,551**	**$ 7.03**	**8.38**	**$ —**
Vested and expected to vest, December 31, 2025	**4,528,555**	**$ 5.74**	**8.73**	**$ —**

**The aggregate intrinsic value is the sum of the amounts by which the quoted market price of the Company's stock exceeded the exercise price of the stock options at December 31, 2025 for those stock options for which the quoted market price was in excess of the exercise price ("in-the-money options").*

The weighted-average grant-date fair value of stock options granted for the years ended December 31, 2025 and 2024, was $2.09 and $6.04, respectively. The total fair value of the stock options that vested during the years ended December 31, 2025 and 2024 was $5,655,038 and $4,034,671, respectively.

The fair value of each stock option grant was estimated on the date of grant using the Black-Scholes option-pricing model under the following assumptions:

	Year Ended December 31,	
	2025	**2024**
Dividend yield	0.00 %	0.00 %
Risk-free interest rate	3.79-4.27%	3.69-4.48%
Expected term (years)	5.27-6.08	5.27-6.08
Volatility	83.86-86.09%	81.73-99.96%

Restricted Stock Units

On February 29, 2024, the Company granted restricted stock units ("RSUs") to its executive management team and to certain members of the Board with market-based vesting conditions. The RSUs are eligible to vest subject to the achievement and attainment of certain market capitalization target goals and share price targets (market-based vesting conditions). The Company used the Monte Carlo Simulation model to evaluate the derived service period and fair value of awards with market and performance conditions, including assumptions of historical volatility and risk-free interest rate commensurate with the vesting term.

The fair value of the Company's market-based RSUs were estimated on the date of grant under the following assumptions:

	Year Ended December 31,
	2024
Dividend yield	0.00%
Volatility factor	93.71%
Risk-free interest rate	4.16%
Derived service periods (years)	1.27 - 2.48

On August 22, 2024, the Board approved a modification to the terms of the RSUs issued on August 25, 2023, and September 29, 2023 to its executive management team and to a member of the Board. The vesting condition was modified from a performance-based condition to a market-based condition. Since the performance condition under the original award was improbable of being met at the time of the modification, no expense was previously recognized. Therefore, on the modification date, the Company established a new fair value and will recognize the expense over the derived service period. The Company used the Monte Carlo Simulation model to evaluate the derived service period and fair value of the awards.

The fair value of the Company's market-based RSUs were estimated on the modification date under the following assumptions:

	August 22, 2024
Dividend yield	0.00%
Volatility factor	94.3%
Risk-free interest rate	3.76%
Derived service periods (years)	2.11

The following is a summary of restricted stock unit activity during the year ended December 31, 2025:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested, December 31, 2024	**503,113**	**$ 9.62**
Granted	—	—
Released	(10,625)	4.80
Unvested, December 31, 2025	**492,488**	**$ 9.72**

The Company used the Monte Carlo Simulation model to evaluate the derived service period and fair value of awards with market and performance conditions, including assumptions of historical volatility and risk-free interest rate commensurate with the vesting term.

Stock-Based Compensation Expense

Stock Compensation Adjustments Related to Board Member Resignations

On July 2, 2024, the Board accepted the resignations of several Board members effective August 1, 2024. Concurrently, the Board approved a modification to the option awards granted such Board members, which modification accelerated the vesting of all unvested options as of the resignation date and extended the post-termination exercise period to December 31, 2025. As a result of the modification, the Company recognized $274,019 in incremental stock compensation expense during the year ended December 31, 2024.

The Company recognizes stock-based compensation expense using the straight-line method over the requisite service period. The Company recognized stock-based compensation expense, including compensation expense for warrants with vesting provisions issued to a service provider (Note 6), and the RSUs discussed above, in its Consolidated Statements of Operations as follows:

	Year Ended December 31,	
	2025	**2024**
Research and development	$ 2,061,154	$ 1,514,921
General and administrative	5,706,540	6,802,559
	$ 7,767,694	**$ 8,317,480**

The total amount of unrecognized compensation cost was $10,276,636 as of December 31, 2025. This amount will be recognized over a weighted-average period of 2.5 years.

2022 Employee Stock Purchase Plan

In June 2022, the Board approved the 2022 Employee Stock Purchase Plan (the "ESPP"), under which the Company may offer eligible employees the option to purchase common stock at a 15% discount to the lower of the market value of the stock at the beginning or end of each participation period under the terms of the ESPP. Total individual purchases in any year are limited to 15% of compensation. The ESPP was approved by the Company's stockholders on September 30, 2022. As of December 31, 2025, 18,461 shares were issued under the ESPP. The compensation expense, computed using the Black-Scholes model was immaterial.

10. Loss Per Share of Common Stock

The following tables are a reconciliation of the numerators and denominators used in the calculation of basic and diluted net loss per share computations:

	For the Year Ended December 31, 2025		
	Loss (Numerator)	**Shares (Denominator)**	**Per-Share Amount**
Net loss	$ (55,924,814)		
Basic EPS and diluted EPS			
Net loss available to common stockholders	(55,924,814)	39,662,664	**$ (1.41)**

	For the Year Ended December 31, 2024		
	Income (Numerator)	**Shares (Denominator)**	**Per-Share Amount**
Net loss	$ (26,567,123)		
Basic EPS and diluted EPS			
Net loss available to common stockholders	(26,567,123)	36,486,519	**$ (0.73)**

The following outstanding shares of common stock equivalents were excluded from the computation of diluted net loss per share of common stock for the periods presented because including them would have been anti-dilutive:

	Year Ended December 31,	
	2025	**2024**
Stock options	4,528,555	3,036,603
Unvested restricted stock units	492,488	503,113
Warrants	3,089,182	3,202,944
Total	8,110,225	6,742,660

11. Income Taxes

The components of loss before the income tax provision consist of the following:

	Year Ended December 31,	
	2025	**2024**
United States	$ (56,242,571)	$ (27,495,672)
Foreign	323,157	938,620
Pre-tax loss from operations	**$ (55,919,414)**	**$ (26,557,052)**

The components of the income tax expense consisted of the following:

	Year Ended December 31,	
Current income tax expense	**2025**	**2024**
Federal	$ —	$ —
State	5,400	10,071
Foreign	—	—
Total current income tax expense	$ 5,400	$ 10,071

The Company is subject to taxation in the United States, various states, Australia, and Canada. The Company's tax years for 2022 (federal), 2021 (States), 2021 (Australia) and 2021 (Canada) and forward are subject to examination by the United States, state, Australian, and Canadian tax authorities. However, to the extent allowed by law, the taxing authorities may have the right to examine periods where NOLs and credits were generated and carried forward and make adjustments up to the amount of the NOL and credit carryforwards. The Company is not currently under examination by any jurisdiction.

At December 31, 2025, the Company had federal and state NOLs aggregating $159,062,533 and $188,066,339, respectively. If not used, $46,622,953 of Federal NOLs and $188,066,339 of state NOLs will begin to expire in 2031, $112,439,580 of federal NOLs will carry forward indefinitely subject to an 80% limitation against taxable income. At December 31, 2025, the Company had Australia NOLs aggregating $453,074 which do not expire and $43,879,070 of Canadian NOLS which begin to expire in 2026.

At December 31, 2025, the Company had Canadian capital loss carryforwards of approximately $35,277,475 which may be carried forward indefinitely.

At December 31, 2025, the Company had federal and California research credit carryforwards of $6,156,218 and $2,445,548, respectively. The federal research credit carry forwards will begin to expire in 2027, unless previously utilized. The California research credits will carry forward indefinitely. The Company's NOLs and research credit carryforwards are subject to a reserve. Additionally, the Company had Canadian SR&ED credits as of December 31, 2025 of $909,791 which may be carried forward indefinitely.

Utilization of the domestic NOL's and research credits could be subject to a substantial annual limitation due to ownership change limitations that may have occurred, or that could occur in the future, as required by Section 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), as well as similar state provisions. These ownership changes may limit the amount of NOLs and credits that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change" as defined by Section 382 of the Code, results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders.

Upon the occurrence of an ownership change under Section 382 as outlined above, utilization of the NOLs and credits are subject to an annual limitation under Section 382 of the Code, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term, tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the NOLs and credits before utilization. While the Company has not performed a Section 382 study, multiple ownership changes may have already occurred as the Company raised capital through the issuance of stock. However, due to the existence of the valuation allowance for deferred tax assets, any potential change in ownership will not impact the Company's effective tax rate.

The tax effects of temporary differences and carryforwards that give rise to significant portions of the deferred income tax assets as of December 31, 2025 and December 31, 2024 are as follows:

	As of December 31,	
Current deferred tax assets and (liabilities):	**2025**	**2024**
Net operating loss	$ 50,218,210	$ 41,627,022
Capital loss carryforwards	9,348,531	14,986,412
Contingent legal accrual	434,504	381,938
Depreciation	42,221	477,024
Amortization	2,298	2,606
Research and development credits	4,953,892	4,112,293
Capitalized research and development costs	7,101,851	4,708,931
Lease liability	57,466	95,674
State taxes	714	1,092
Stock-based compensation	1,899,512	1,174,967
Other	331,584	270,088
Gross deferred tax assets	**74,390,783**	**67,838,047**
Valuation allowance	(74,334,787)	(67,743,575)
Net deferred tax assets	**$ 55,996**	**$ 94,472**
Deferred tax liabilities		
Right-of-use asset	$ (55,996)	$ (94,472)
Total deferred tax liabilities	**(55,996)**	**(94,472)**
Net deferred tax assets	**$ —**	**$ —**

A reconciliation of the provision for income taxes to the amount computed by applying the 21% statutory U.S. federal income tax rate to income (loss) from continuing operations before income taxes after the adoption of ASU 2023-09 is as follows:

	As of December 31, 2025	
Tax at Statutory Rate	(11,743,077)	21.00 %
State and local income tax, net of federal income tax effect [a]	4,265	(0.01) %
Tax credits	(695,831)	1.24 %
Change in valuation allowance	11,477,094	(20.52) %
Nondeductible executive compensation under 162(m)	740,965	(1.33) %
Other	175,360	(0.31) %
Nontaxable or nondeductible items, Total	*916,325*	*(1.64) %*
Foreign tax effects		
Canada		
Change in valuation allowance	(5,030,006)	9.00 %
Change in foreign currency valuation	(1,057,734)	1.89 %
Capital loss carryforwards no longer available	6,089,631	(10.89) %
Other	(78,645)	0.14 %
Other foreign jurisdictions	8,892	(0.02) %
Foreign tax effects, Total	(67,862)	0.12 %
Other	114,486	(0.20) %
Total	**$ 5,400**	**(0.01)%**

[a] The State of California comprises greater than 50 percent of the state tax expense for the period ended December 31, 2025.

The provision for income taxes on earnings subject to income taxes differs from the statutory Federal rate at December 31, 2024, due to the following:

	As of December 31, 2024
Expected income tax benefit at federal statutory tax rate	$ (5,576,981)
State income taxes, net of federal benefit	(1,871,588)
Change in valuation allowance	2,522,618
Uncertain tax positions	2,562,991
Reduction in deferreds upon divestiture	839,873
Stock compensation	(46,422)
Research and development credits	(1,374,591)
Rate adjustment	6,070
Foreign rate differential	2,396,433
162(m) officers compensation	460,853
Other	90,815
Provision for income taxes	**$ 10,071**

The Company records a valuation allowance against deferred tax assets to the extent that it is more likely than not that some portion, or all of, the deferred tax assets will not be realized. Due to the substantial doubt related to the Company's ability to utilize its deferred tax assets, a valuation allowance for the full amount of the deferred tax assets has been established at December 31, 2025. During the year ended December 31, 2025, the valuation allowance increased by $6,591,212.

Under the FASB's accounting guidance related to income tax positions, among other things, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, the guidance provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

A reconciliation of the beginning and ending amounts of unrecognized tax positions are as follows:

	As of December 31,	
	2025	**2024**
Unrecognized tax benefits, beginning of the year	**$ 9,498,441**	**$ 6,432,143**
Gross increase – current period tax positions	5,033,976	3,073,575
Gross decrease – prior period tax positions	(397)	(7,277)
Unrecognized tax benefits, end of year	**$ 14,532,020**	**$ 9,498,441**

If recognized, none of the unrecognized tax positions would impact the Company's income tax benefit or effective tax rate as long as the Company's net deferred tax assets remain subject to a full valuation allowance.

The Company had no accrual for interest or penalties on the Company's Consolidated Balance Sheets at December 31, 2025 and 2024 and has not recognized interest and/or penalties in the Consolidated Statements of Operations for the years then ended.

12. Commitments and Contingencies

Office Leases

The Company leases office space for its corporate headquarters, located at 11250 El Camino Real, Suite 100 San Diego, California 92130. The original lease term was effective from September 1, 2021 through October 31, 2023 and contained a renewal option for a two-year extension after the current expiration date. At the commencement date, the Company did not expect to exercise the renewal option, and has therefore excluded the option from the calculation of the right of use asset and lease liability. The lease provides for two months of rent abatement and the initial monthly rent is $8,067 per month with annual increases of 3% commencing on November 1, 2022. The lease included non-lease components (i.e., property management costs) that are paid separately from rent, based on actual costs incurred, and therefore were not included in the right-of-use asset and lease liability but are reflected as an expense in the period incurred. In calculating the present value of the lease payments, the Company has elected to utilize its incremental borrowing rate based on the lease term.

The Company entered into an amended and restated lease agreement on June 27, 2023 for its corporate headquarters, extending the lease term to 36 months, retroactive to September 1, 2021 through October 31, 2026. The Company treated the amended and restated lease agreement as a single modified lease.

On September 25, 2024, the Company entered into a new lease agreement for approximately 2,077 square feet of office space located at 632 Commercial Street, 5th Floor, San Francisco, California 94111. The lease has a term of three years and two months, beginning on October 01, 2024, with a monthly rent of $9,000 and annual increases of 3%. This office space will support the Company's continued growth and operational needs as the Company expands its development activities. In calculating the present value of the lease payments, the Company has elected to utilize its incremental borrowing rate based on the lease term.

For the years ended December 31, 2025 and 2024, lease expense comprised of $207,400 and $130,658, respectively in lease cost from the Company's non-cancellable operating leases.

The remaining lease term and discount rate related to the operating lease are presented in the following table:

	December 31, 2025
Weighted-average remaining term – operating lease (in years)	1.74
Weighted-average discount rate – operating lease	10.75 %

Future minimum lease payments as of December 31, 2025 are presented in the following table:

Year:	
2026	202,876
2027	85,936
Total future minimum lease payments:	288,812
Less imputed interest	15,166
Total	**$ 273,646**

Reported as:

	December 31, 2025	December 31, 2024
Operating lease liability	$ 189,647	$ 182,428
Operating lease liability, net of current portion	83,999	273,162
Total lease liability	**$ 273,646**	**$ 455,590**

General Litigation and Disputes

From time to time, in the normal course of operations, the Company may be a party to litigation and other dispute matters and claims. Litigation can be expensive and disruptive to normal business operations. Moreover, the results of complex legal proceedings are difficult to predict. An unfavorable outcome to any legal matter, if material, could have a materially adverse effect on the Company's operations or financial position, liquidity or results of operations.

Wendy Cunning vs Skye Bioscience, Inc.

The Company is a party to a legal proceeding with a former employee alleging, among other things, wrongful termination, violation of whistleblower protections under the Sarbanes-Oxley Act of 2002, and retaliation under California law against the Company relating to certain actions and events that occurred with the Company's former management during the employee's employment term from March 2018 to July 2019. The case, entitled *Wendy Cunning vs Skye Bioscience, Inc.*, was filed in U.S. District Court (the "District Court") for the Central District of California (the "Cunning Lawsuit"). On January 18, 2023, a jury rendered a verdict in favor of Ms. Cunning and awarded her $512,500 in economic damages (e.g., lost earnings, future earnings and interest), $840,960 in non-economic damages (e.g., emotional distress) and $3,500,000 in punitive damages. On August 2, 2023, the District Court ruled on the plaintiff's motion for attorney fees and awarded the plaintiff $1,200,008. Based on this order, the Company reduced the aggregate estimate for the legal contingency by $151,842, the difference between the attorney fees awarded by the District Court and the Company's previous estimate. On August 17, 2023, the Company obtained a stay on enforcement of the judgment in the Cunning Lawsuit by posting an appeal bond in the amount of $9,080,202.

In March of 2023, the Company appealed the judgment in the Cunning Lawsuit to the United States Court of Appeals for the Ninth District (the "Ninth Circuit"). Subsequent to quarter end, on October 22, 2024, the Ninth Circuit issued its decision in the Company's favor which vacated the judgment and remanded the case back to the District Court for a new trial. As a result, the Company recovered the $9,080,202 restriction on its cash related to the bond during the year ended December 31, 2024. The District Court has tentatively set a new trial date in March 2026.

During the year ended December 31, 2024, management revised its assumptions related to its estimate of the legal contingency and the Company reversed the accrued interest on the original judgment and recognized a gain of $4,234,717 in change in estimate for legal contingencies. As of December 31, 2025, the estimated legal contingency, including accrued legal expenses is $2,069,067.

In arriving at the conclusion that a significant portion of the estimated legal contingency should be reversed, the Company considered the following in revising its assumptions:

- Advice from external advisors including its technical accounting advisors regarding the appropriate application of GAAP and legal counsel's advice with regard to prior experience with similar cases,
- the damages and potential attorney fee awards if the case were to be retried, including the likelihood of a subsequent loss if the Company were to be unsuccessful while giving consideration to the facts and circumstances that would be inadmissible due to the Ninth Circuit's decision,
- the likelihood of settlement and information obtained during settlement discussions prior to the first trial,
- the Company's possible defenses and counterclaims, and

- the case history and the amount of the prior judgment.

The final amount of the loss and loss recoveries remain uncertain. The ultimate amount of the potential loss may be significantly less than the amount of the revised legal contingency and there is no guarantee that the Company will be successful in its efforts to recover additional losses. The Company believes that it is at least reasonably possible that the estimated amount of the potential loss may change in the near term.

Securities Class Action and Derivative Lawsuit

A putative securities class action lawsuit was filed on November 17, 2025, in the United States District Court for the Southern District of California, captioned *Stout v. Skye Bioscience, Inc.*, et al., Case No. 3:25-cv-03177-WQH. The complaint asserts that the Company and certain of the Company's executives violated Section 10(b) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and SEC Rule 10b-5, by making materially false or misleading statements related to the efficacy of and prospects for nimacimab between November 4, 2024 and October 3, 2025. The plaintiff also alleges that the Company's executives, whom they named as defendants, violated Section 20(a) of the Exchange Act. The plaintiff seeks class certification, an award of unspecified damages, an award of costs and expenses, including attorneys' fees and expert fees, and further relief as the Court may deem just and proper. On January 16, 2026, two stockholders moved to be appointed lead plaintiff.

A putative derivative lawsuit was filed on January 29, 2026, in the United States District Court for the Southern District of California, captioned *Domulot v. Dhillon et al.*, Case No. 3:26-cv-00600-WQH. The lawsuit asserts claims, purportedly on behalf of the Company, against certain officers and directors of the Company for breach of fiduciary duty, unjust enrichment, abuse of control, gross mismanagement, waste of corporate assets, violations of Sections 14(a) of the Exchange Act, and for contribution under Sections 10(b) and 21D of the Exchange Act based on the dissemination of allegedly false and misleading statements related to nimacimab. The plaintiff seeks unspecified damages, an award of costs and expenses, including attorneys' fees and expert fees, and other relief, including corporate governance reforms.

License Agreement with Halozyme

On December 18, 2025, the Company entered into a Non-exclusive Collaboration and License Agreement (the "Halozyme License Agreement") with Halozyme, Inc. ("Halozyme").

Under the terms of the Halozyme License Agreement, Halozyme granted the Company a non-exclusive license to Halozyme's ENHANZE® drug delivery technology for the development of a subcutaneous formulation of nimacimab (such combination, the "Product"). Halozyme will also be the Company's exclusive supplier of clinical and commercial supplies of the API for Halozyme's rHuPH20 bulk drug product.

Among other considerations, the Company will make milestone payments to Halozyme tied to achievement of certain development and commercialization milestone events with respect to the Product, as well as milestone payments based on achievement of certain net sales levels of the Product. The Company will also make mid-single digit royalty payments based on worldwide net sales of the Product. To date, none of such milestones has been achieved.

The Halozyme License Agreement became effective in December 2025 and, unless earlier terminated, will continue until the expiration of the royalty term for the applicable product in each country, which begins upon the first commercial sale of the product in such country and continues until the last valid patient claim covering the product in that country or the length of time specified in the Halozyme License Agreement. The Halozyme License Agreement also includes customary termination rights, representations and warranties, covenants and indemnification obligations for a transaction of this nature.

13. Segment Reporting

The Company operates in one business segment, which includes the business of research and development activities related to developing medicine for obesity and metabolic diseases. The determination of a single business segment is consistent with the consolidated financial information regularly provided to the Company's chief operating decision maker ("CODM"). The Company's CODM is its Chief Executive Officer, who reviews and evaluates consolidated net loss for purposes of assessing performance, making operating decisions, allocating resources, and planning and forecasting for future periods.

In addition to the significant expense categories included within consolidated net loss presented on the Company's Consolidated Statements of Operations, see below for disaggregated amounts that comprise research and development expenses which are presented to the Company's CODM for review:

	Year Ended December 31,	
	2025	**2024**
External clinical development expenses [1]		
SBI-100	$ 10,511	$ 2,216,209
nimacimab	32,305,827	10,801,849
Total external clinical development expenses	32,316,338	13,018,058
Personnel related and stock-based compensation	5,928,398	3,995,558
Other research and development expenses [2]	4,117,143	1,688,078
Total research and development expenses	**$ 42,361,879**	**$ 18,701,694**

(1) External clinical development expenses include expenses for clinical trial costs and clinical manufacturing, as well as costs for discovery in research and development studies.
(2) Other research and development expenses include expenses for travel and entertainment, consulting and advisory and general business expenses.

The amount of property and equipment in the US was equal to $55,488, and $83,276 for December 31, 2025 and December 31, 2024, respectively. The amount of property and equipment outside of the US was equal to $843,442, and $1,349,476 for December 31, 2025 and December 31, 2024, respectively.

14 Subsequent Events

Subsequent to December 31, 2025, the Company granted an aggregate of 1,367,800 common stock options to members of management, employees and directors under the Amended and Restated Plan.

Concurrently, with the separation of the Company's Chief Financial Officer, on February 20, 2026 (the "Separation Date"), the Board approved a modification to the option awards granted Ms Arsenault, which extended the post-termination exercise period to the later of February 20, 2027, or ninety (90) days after the expiration of her Advisor Agreement. In addition, in the event of a change in control within one year from the Separation Date, 100% of Ms. Arsenault's equity will vest immediately prior to the consummation of such change in control.

On February 18, 2026, the Company formally requested to terminate its lease for the San Francisco office effective 60 days after the notice. As a result of this termination, the Company will derecognize a right-of-use asset and lease liability of approximately $170,000 in the first quarter of 2026. The Company has also initiated a claim for the full refund of its security deposit related to this termination.

The following exhibits are filed with this Annual Report on Form 10-K.

Exhibit Number	Description of Exhibit
2.1	Arrangement Agreement, dated May 11, 2022, by and between the Company and EHT (incorporated by reference to Exhibit 2.1 to our Current Report on Form 8-K filed on May 11, 2022)
2.2	Amendment No. 1 to the Arrangement Agreement, dated June 14, 2022, by and between the Company and EHT (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on June 17, 2022)
2.3	Amendment No. 2 to the Arrangement Agreement, dated July 15, 2022, by and between the Company and EHT (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on July 21, 2022)
2.4	Amendment No. 3 to the Arrangement Agreement, dated October 18, 2022, by and between the Company and EHT (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on October 19, 2022)
2.6	Share Purchase Agreement, dated November 8, 2022, by and between Emerald Health Therapeutics, Inc., 14428773 Canada Inc., Verdelite Sciences, Inc., Verdelite Property Holdings, Inc. and C3 Centre Holding Inc. (incorporated by reference to Exhibit 10.3 to our Quarterly Report on Form 10-Q filed on November 14, 2022)
2.7	Amendment No. 1 to the Share Purchase Agreement, dated January 26, 2023, by and between Emerald Health Therapeutics, Inc., 14428773 Canada Inc., Verdelite Sciences, Inc., Verdelite Property Holdings, Inc. and C3 Centre Holding Inc. (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on January 27, 2023)
2.8	Amendment No. 2 to the Share Purchase Agreement, dated February 9, 2023, by and between Emerald Health Therapeutics, Inc., 14428773 Canada Inc., Verdelite Sciences, Inc., Verdelite Property Holdings, Inc. and C3 Centre Holding Inc. (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on February 15, 2023)
2.9	Agreement and Plan of Merger and Reorganization, dated August 15, 2023, by and among Skye Bioscience, Inc., Aquila Merger Sub, Inc., and Bird Rock Bio, Inc. (incorporated by reference to Exhibit 2.9 to our Annual Report on Form 10-K filed on March 22, 2024)
3.1	Articles of Incorporation of Registrant, as amended (incorporated by reference to Exhibit 3.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 22, 2024)
3.2	Amended and Restated Bylaws of Registrant (incorporated by reference to Exhibit 3.2 to our Report on Form 10-K filed on March 2, 2021)
4.1	2016 Form of Common Stock Warrant (incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed August 20, 2015)
4.2	2021 Inducement Warrants (incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q filed November 10, 2021)
4.3	2021 Common Stock Warrants (incorporated by reference to Exhibit 4.1 to our Quarterly Report on Form 10-Q filed November 10, 2021)
4.4	2021 Common Stock Warrants to Placement Agent (incorporated by reference to Exhibit 4.3 to our Quarterly Report on Form 10-Q filed November 10, 2021)
4.5	2023 Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed on August 21, 2023)
4.6	2023 Common Stock Purchase Warrant issued by Skye Bioscience, Inc. to MFDI, LLC (incorporated by reference to Exhibit 4.3 to our Current Report on Form 8-K filed on August 21, 2023)
4.7	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed on January 29, 2024)
4.8	Amendment to Common Stock Purchase Warrants (incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed on March 13, 2024)
4.9	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (incorporated by reference to our Annual Report on Form 10-K filed on March 20, 2025)
10.1†	Skye Bioscience, Inc. Amended and Restated Omnibus Incentive Plan and form of stock option agreements and form of restricted stock agreements thereunder (incorporated by reference to Exhibit 10.1 to our Annual Report on Form 10-K filed on March 20, 2025)

10.2†	Skye Bioscience, Inc. Amended and Restated 2024 Inducement Equity Incentive Plan and form of stock option agreement and form of restricted stock agreement thereunder (incorporated by reference to Exhibit 10.2 to our Annual Report on Form 10-K filed on March 20, 2025)
10.3†	Skye Bioscience, Inc. 2022 Employee Stock Purchase Plan (incorporated by reference to Appendix C to our definitive proxy statement filed on August 31, 2022)
10.4†	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on January 12, 2015)
10.5†	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.4 to our Current Report on Form 8-K filed on August 21, 2023)
10.6†	Employment Agreement, dated August 10, 2020, by and between Skye Bioscience, Inc. and Punit Dhillon (incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed on August 12, 2020)
10.10†	Employment Agreement, dated October 5, 2020, by and between Skye Bioscience, Inc. and Tu Diep (incorporated by reference to Exhibit 10.10 to our Annual Report on Form 10-K filed on March 20, 2025)
10.11†	Employment Agreement, dated November 11, 2022 by and between Skye Bioscience, Inc. and Chris Twitty (incorporated by reference to Exhibit 10.11 to our Annual Report on Form 10-K filed on March 20, 2025)
10.12**	Securities Purchase Agreement, dated as of August 15, 2023, by and among Skye Bioscience, Inc. and the Investors named therein (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on August 21, 2023)
10.13**	Registration Rights Agreement, dated as of August 15, 2023, by and among Skye Bioscience, Inc. and the Investors named therein (incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed on August 21, 2023)
10.14**	Secured Note and Warrant Purchase Agreement, dated as of August 15, 2023, by and among Skye Bioscience, Inc. and MFDI, LLC (incorporated by reference to Exhibit 10.3 to our Current Report on Form 8-K filed on August 21, 2023)
10.15**	Form of Securities Purchase Agreement, dated as of January 29, 2024, by and among Skye Bioscience, Inc. and the Investors named therein (incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q filed on May 10, 2024)
10.16**	Form of Securities Purchase Agreement, dated as of March 11, 2024, by and among Skye Bioscience, Inc. and the Investors named therein (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on March 13, 2024)
10.17**	Form of Registration Rights Agreement, dated as of March 11, 2024, by and among Skye Bioscience, Inc. and the Investors named therein (incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed on March 13, 2024)
10.18	Equity Distribution Agreement, dated as of May 10, 2024, by and between Skye Bioscience, Inc. and Piper Sandler & Co. (incorporated by reference to Exhibit 1.2 to our Registration Statement on Form S-3 filed on May 10, 2024)
10.19	Office Lease, dated as of August 25, 2021, by and between ROIC California, LLC and the Company (incorporated by reference to Exhibit 99.1 to our Current Report on Form 8-K filed on September 15, 2021)
10.20#	Non-Exclusive Collaboration and License Agreement, dated December 18, 2025, by and between the Company and Halozyme, Inc.
19	Skye Bioscience, Inc. Insider Trading Policy (incorporated by reference to Exhibit 19 to our Annual Report on Form 10-K filed on March 20, 2025)
20#	Skye Bioscience, Inc. Code of Business Conduct and Ethics
21.1#	Subsidiaries of the Registrant
23.1#	Consent of CBIZ CPAs PC
23.2#	Consent of Marcum LLP
31.1#	Certification of Principal Executive Officer, pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934
31.2#	Certification of Principal Financial and Accounting Officer, pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934

32.1#	Certification of Principal Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2#	Certification of Principal Financial and Accounting Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97.1†	Policy relating to recovery of erroneously awarded compensation, as required by applicable listing standards adopted pursuant to 17 CFR 240.10D-1 (incorporated by reference to Exhibit 97.1 to our Annual Report on Form 10-K filed on March 22, 2024)
101#	Inline XBRL Document Set for the consolidated financial statements and accompanying notes in Part II, Item 8, "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

_____
Filed Herewith
** Portions of this exhibit have been omitted in compliance with Regulation S-K Item 601(b)(10)(iv).
† Management contract or compensatory plan or arrangement.

Item 16. Form 10-K Summary.

None.

SIGNATURES

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

Skye Bioscience, Inc.
a Nevada corporation

March 10, 2026

By: *\/s\/ Punit Dhillon*
Punit Dhillon
Its: Director, Chief Executive Officer
(Principal Executive Officer & Principal Financial and Accounting Officer)

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

By: *\/s\/ Punit Dhillon* March 10, 2026
Punit Dhillon
Its: Director, Chief Executive Officer
(Principal Executive Officer &
Principal Financial and Accounting Officer)

By: *\/s\/ Paul Grayson* March 10, 2026
Paul Grayson
Its: Director, Chairman

By: *\/s\/ Deborah Charych* March 10, 2026
Deborah Charych
Its: Director

By: *\/s\/ Andrew J. Schwab* March 10, 2026
Andrew J. Schwab
Its: Director

By: *\/s\/ Karen Smith* March 10, 2026
Karen Smith
Its: Director

By: *\/s\/ Annalisa Jenkins* March 10, 2026
Annalisa Jenkins
Its: Director

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICY DISCLOSED

NON-EXCLUSIVE COLLABORATION AND LICENSE AGREEMENT

THIS NON-EXCLUSIVE COLLABORATION AND LICENSE AGREEMENT (this "Agreement"), effective as of December 18, 2025 (the "Effective Date"), is entered into by and between Halozyme, Inc., a California corporation located at 12390 El Camino Real, San Diego, CA 92130 ("Halozyme"), and Skye Bioscience, Inc., a Nevada corporation located at 11250 El Camino Real, Suite 100, San Diego, CA 92130 ("Company"). Each of Halozyme and Company may be referred to, individually, as a "Party", and, collectively, as the "Parties."

RECITALS

WHEREAS, Halozyme is the owner or exclusive licensee of certain patents, formulations and know-how related to the PH20 Drug (defined below);

WHEREAS, Company is the owner or exclusive licensee of certain patents and know-how related to the Company Biologic (defined below);

WHEREAS, on the terms and conditions herein, Company desires a license from Halozyme in connection with researching and developing Products (defined below) for approval, and commercializing such Products in the Field (defined below); and

WHEREAS, on the terms and conditions herein, Halozyme is willing to non-exclusively license to Company certain intellectual property rights under the PH20 Drug and to collaborate with Company in connection with Company's research, development, approval, and commercialization of such Products in the Field.

AGREEMENT

NOW, THEREFORE, for mutual consideration, the receipt and sufficiency of which is acknowledged, the Parties agree as follows:

1. DEFINITIONS.

Capitalized terms used in this Agreement (including the Exhibits and Schedules attached hereto) shall have the following meanings (or as defined elsewhere in the Agreement):

1.1 "Acquirer" has the meaning set forth in the definition of Change of Control.

1.2 "Affiliate" means, with respect to a person or entity, any person, corporation or business entity that, at the relevant time (whether as of the Effective Date or thereafter), directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such person or entity. For purposes of this definition, "control" means (a) the possession of the power to, directly or indirectly, direct or cause the direction of the management and policies of a corporation or business entity, whether through ownership of voting securities or by contract relating to voting rights or corporate governance, or (b) direct or indirect ownership of fifty percent (50%) or more of the securities or other ownership interests representing the equity, the voting stock or, if applicable, the general partnership interest of such corporation or business.

1.3 "Agreement" has the meaning set forth in the preamble.

1.4 "API" means [***].

1.5 "API Specifications" means the specifications set forth in Schedule 1.5.

1.6 "Arbitration Center" has the meaning set forth in Section 12.1.

1.7 "Background IP" has the meaning set forth in Section 8.1.

1.8 [***]

1.9 "Biologic" means a biological product as defined in 42 USC § 262(i), as such statute may be amended from time to time.

1.10 "Business Day" means a weekday on which banking institutions in the United States are generally open for business.

1.11 "cGMP" means the principles detailed in (a) the United States Current Good Manufacturing Practices (21 C.F.R. Parts 4, 210, 211, 600, 601, and 610), (b) the "Rules Governing Medicinal Product in The European Community - Volume IV Good Manufacturing Practice for Medicinal Products," and/or "Cooperative Manufacturing Arrangements for Licensed Biologics" FDA-CBER, (c) WHO TRS 986 Annex 2, TRS 961 Annex 6, TRS 957 Annex 2 and TRS 999 Annex 2, (d) ICH Q7 guidelines, and (e) any applicable equivalent Regulatory Authority requirements and regulations.

1.12 "Change of Control" means, with respect to a Party, (a) a merger, consolidation, recapitalization, or reorganization of such Party with a Third Party that results in the holders of beneficial ownership (other than by virtue of obtaining irrevocable proxies for purposes of management voting on matters as directed by beneficial owners) of the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to hold beneficial ownership of more than fifty percent (50%) of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger, consolidation, recapitalization, or reorganization, (b) a transaction or series of related transactions in which a Third Party becomes the direct or indirect beneficial owner of more than fifty percent (50%) of the combined voting power of the outstanding securities of such Party, (c) the sale or transfer of all or substantially all of the assets of such Party and its controlled Affiliates, (d) the acquisition of majority control of the board of directors or equivalent governing body of such Party, (e) the acquisition of the ability to cause the direction of the management or allocation of corporate resources of such Party, or (f) the acquisition of all or substantially all of the assets of such Party related to the transactions contemplated by this Agreement. Notwithstanding the foregoing, any transaction or series of transactions effected solely for the purpose of changing the form or jurisdiction of

organization of such Party (such as an initial public offering or other offering of equity securities to non-strategic investors or corporate reorganization) will not be deemed a "Change of Control" for purposes of this Agreement. The acquiring or combining Third Party in any of the foregoing (a), (b) or (c), and any of such Third Party's Affiliates (whether in existence as of or at any time following the applicable transaction, but other than the acquired Party and its Affiliates as in existence prior to the applicable transaction or Affiliates the acquired Party controls after the applicable transaction) are referred to collectively herein as the "Acquirer."

1.13 "Clinical Supply" has the meaning set forth in Section 7.1.

1.14 "Collaboration Invention" means any invention or discovery, whether or not patentable (including a modification, improvement or new use), that is first conceived or reduced to practice pursuant [***]. For the avoidance of doubt, for purposes of this definition, each Party's activities shall include all activities of such Party's Affiliates and their respective employees, contractors and sublicensees.

1.15 "Collaboration Supported Company Biologic Patents" means [***].

1.16 "Collaboration Supported Other Patents" has the meaning set forth in Section 8.1.4.

1.17 "Collaboration Supported Patents" means [***].

1.18 "Collaboration Supported PH20 Patents" means [***].

1.19 "Collaboration Supported Product IP" has the meaning set forth in Section 8.1.3.

1.20 "Collaboration Supported Product Patents" means [***].

1.21 "Commercial Supply" has the meaning set forth in Section 7.1.

1.22 "Commercial Supply Agreement" has the meaning set forth in Section 7.1.

1.22 "Commercially Reasonable Efforts" means the level of efforts and resources of a Party required to, [***] consistent with the efforts[***].

1.23 "Company" has the meaning set forth in the preamble.

1.24 "Company Biologic" means any proprietary Biologic or compound that is a single molecular entity owned or licensed by Company where the primary therapeutic effect of such Biologic or compound arises from the binding of such Biologic or compound to the Company Target and no other Target.

1.25 "Company Biologic Collaboration Inventions" has the meaning set forth in Section 8.1.1.

1.26 "Company Indemnitees" has the meaning set forth in Section 10.2.

1.27 [***].

1.28 "Company Solely-Owned Patents" has the meaning set forth in Section 8.4.2.

1.29 "Company Target" means the Cannabinoid Receptor 1 (CB-1) Target described as GenBank accession number NM_016083.

1.30 "Confidential Information", as to a Party (or its Affiliates), means non-public information provided to the other Party (or its Affiliates) under this Agreement, whether written, oral, or visual, including technologies, current and proposed product and/or service information, research, development, scientific or financial data, compilations, formulae, models, design details, patent disclosures, procedures, processes, projections, protocols, results of experimentation and testing, specifications, strategies and techniques, business forecasts, sales information, pricing, manufacturing information and assets. Notwithstanding the foregoing, "Confidential Information" of a Party shall not include any such information of any [***], when referring to information to be provided by Halozyme to Company.

1.31 "Control" means, with respect to any item or right, the possession of or the ability of a person or its Affiliates (in each case whether by ownership or license, other than pursuant to this Agreement), at the relevant time, to grant access to, or a license or sublicense of, such item or right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party existing at the time such person would be required hereunder to grant such access or license or sublicense, or requiring consent from any such Third Party; and "Controlled" shall be interpreted accordingly.

1.32 "Convicted Entity" has the meaning set forth in Section 2.2.8(d).

1.33 "Convicted Individual" has the meaning set forth in Section 2.2.8(d).

1.34 "Cover" or "Covering" means (a) as used in relation to a Patent Right and a product, that such Patent Right would be infringed by the [***]of such product, including infringement of patent claims [***]; and (b) as used in relation to a Patent Right and an invention, that such Patent Right claims such invention. As used in this definition, pending patent claims will be considered as if they had been issued in the form in which they are pending at the time "Coverage" is considered.

1.35 "CMO" has the meaning set forth in Section 7.1.

1.36 "CRO" has the meaning set forth in Section 5.2.2.

1.37 "Debarred Entity" has the meaning set forth in Section 2.2.8(b).

1.38 "Debarred Individual" has the meaning set forth in Section 2.2.8(a).

1.39 "Defective API" has the meaning set forth in Section 7.4.3.

1.40 "Disclosing Party" has the meaning set forth in Section 9.1.

1.41 "DMF" means a Drug Master File filed with the FDA, EMA, MHLW or another foreign equivalent.

1.42 "Effective Date" has the meaning set forth in the preamble.

1.43 "EMA" means the European Medicines Agency of the European Union, or the successor thereto.

1.44 "Enforcing Party" has the meaning set forth in Section 8.4.4.

1.45 "European Union" or "EU" means the countries of the European Economic Area, as it is constituted on the Effective Date and as it may be modified from time to time after the Effective Date.

1.46 "Excluded Entity" has the meaning set forth in Section 2.2.8(c).

1.47 [***]

1.48 "Excluded Individual" has the meaning set forth in Section 2.2.8(c).

1.49 [***]

1.50 "FDA" means the United States Food and Drug Administration, or the successor thereto.

1.51 "FDA's Disqualified/Restricted List" has the meaning set forth in Section 2.2.8(e).

1.52 "Field" means all human and non-human diagnostic, therapeutic, and prophylactic uses.

1.53 "Firewalls" means reasonable safeguards (including walls and screens) established between Company, on the one hand, and on the other hand, the [***], to ensure that no non-public information, materials [***] or non-personnel resources [***], or any non-public information, materials or non-personnel resources relating to [***] that were provided, made accessible, licensed or sublicensed to [***].

1.54 "First Commercial Sale" means, with respect to a Product and a given country, the first commercial sale of a Product in such country by Company or its Affiliates or any of its or their permitted sublicensees to a Third Party that is not a sublicensee (after all applicable Regulatory Approvals have been granted by the applicable Regulatory Authority), [***].

1.55 "FTE" means the equivalent of the work of one qualified employee or agent for the applicable activities, full time, for one year (constituting [***]working hours). An individual contributing work for less than [***]hours per year shall be treated as an FTE on a pro-rata basis, based upon the actual number of hours worked by such person on the applicable activities, divided by [***]. No person shall be treated as being more than one FTE regardless of the number of hours worked.

1.56 "FTE Rate" means $[***] per hour or $[***]for [***]hours per year, as may be updated pursuant to Section 1.44.

1.57 "Fully Burdened Manufacturing Cost" means Halozyme's reasonable and necessary internal and Third Party costs incurred in manufacturing or acquiring API, including [***].

1.58 "Fully Burdened Work Plan Cost" means the cost to conduct the research and development activities to be conducted by Halozyme as set forth in the Work Plan calculated on the product of (a) [***], and (b) [***].

1.59 "Halozyme" has the meaning set forth in the preamble.

1.60 "Halozyme Assay" has the meaning set forth in Section 5.2.2.

1.61 "Halozyme Indemnitees" has the meaning set forth in Section 10.1.

1.62 [***]

1.63 "Halozyme Prosecuted Patents" has the meaning set forth in Section 8.4.1(a).

1.64 [***].

1.65 "ICDR" or the "Arbitration Center" has the meaning set forth in Section 12.1.

1.66 "Indemnitee" has the meaning set forth in Section 10.3.

1.67 "Indemnitor" has the meaning set forth in Section 10.3.

1.68 "Initiation" means the first patient dosed, in any treatment arm, in the applicable clinical trial to evaluate a Product.

1.69 "Know-How Rights" means, whether or not patentable or otherwise protected by trade secret law, any and all know-how, including knowledge that is technical, scientific, regulatory, and/or business-related (including research, development, and commercial); analysis; assistance; data and information (including clinical and regulatory data and information related to plasmids, proteins, cell lines, assays and compounds); designs; efficiencies; experience; formulae; ideas; improvements; instructions; inventions; means; methods; modeling (including pharmacokinetic, pharmacodynamics, and translational modeling); pharmacovigilance know-how; processes; practices; procedures; programs; quality, supply chain, and manufacturing know-how; safety information; skills; specifications; studies; techniques; tests; and toxicology results; in any form and irrespective of whether the foregoing is confidential, proprietary, patented (or patentable), and any modifications, variations, derivative works and improvements of or relating to any of the foregoing.

1.70 "Liabilities" has the meaning set forth in Section 10.1.

1.71 "Licensed IP Rights" means, collectively, the Licensed Know-How Rights and Licensed Patent Rights. For avoidance of doubt, the "Licensed IP Rights" do not include any [***].

1.72 "Licensed Know-How Rights" means all Know-How Rights relating to the PH20 Drug that are (a) Controlled by Halozyme or its Affiliate(s) [***] as of the Effective Date, or (b) discovered, created, conceived, or reduced to practice by Halozyme or its Affiliate(s) [***] during the Term and Controlled by Halozyme or its Affiliate(s) [***] [***]; that, in each case of the foregoing (a) and (b), are [***] to develop, obtain Regulatory Approval for, manufacture, commercialize, or use Products. [***].

1.73 "Licensed Marks" means the HALOZYME name and ENHANZE mark, or such other trademarks, trade names, designs and markings Controlled by Halozyme and designated from time to time in writing by Halozyme for use by Company under this Agreement pursuant to Article 5.

1.74 "Licensed Patent Rights" means all Patent Rights in the Territory that (a) are Controlled by Halozyme or its Affiliate(s) [***] as of the Effective Date, or (b) claim inventions that are discovered, created, conceived, or reduced to practice by Halozyme or its Affiliate(s) [***] during the Term and Controlled by Halozyme or its Affiliate(s) [***]; that, in each case of the foregoing (a) and (b), Cover any Product, [***], and any Collaboration Supported Patent owned by Halozyme pursuant to Section 8.1. "Licensed Patent Rights" includes the Patent Rights listed on Exhibit A and the Collaboration Supported PH20 Patents, but for the avoidance of doubt, does not include any [***].

1.75 "MHLW" means the Ministry of Health, Labour and Welfare of Japan, or the successor thereto.

1.76 "NDA/BLA/MAA" means a Biologics License Application ("BLA") or New Drug Application ("NDA") submitted to the FDA or a Market Authorization Application ("MAA") submitted to the EMA or MHLW, or any supplemental filing to a BLA, NDA or MAA that is relevant to the Product being developed.

1.77 "Net Sales" means, with respect to any Product following Regulatory Approval, the gross amounts invoiced by Company or any of its Affiliates, or any of its or their permitted sublicensees (each, a "Selling Party"), to a Third Party for sales of such Product, less, to the extent actually paid, allowed, taken, incurred, allocated or accrued by the Selling Party (as applicable) for:

1.77.1 [***]

1.78 All [***] deductions shall be fairly and equitably allocated to such Product and other products of the Selling Party and its Affiliates such that such Product does not bear a disproportionate portion of such deductions. Any deductions that satisfy more than one of the foregoing criteria shall only be deducted once for purposes of calculating Net Sales. For clarity, "Net Sales" shall not include sales and marketing expenses or transfers or dispositions for charitable, promotional, pre-clinical, clinical, regulatory, or governmental purposes, to the extent provided without charge or sold for no more than the manufacturing costs thereof, but shall include commercial sales to government purchasers Notwithstanding the foregoing, all deductions applied to Net Sales shall be in accordance with U.S. GAAP from the books and records of the applicable Selling Party or, [***], such similar accounting principles, consistently applied. In determining such amounts, the [***].

1.79 When determining Net Sales, if Company or its Affiliates, or its or their sublicensees, sells a Product to a Third Party who also purchases other products or services from Company, its sublicensees or their respective Affiliates, and Company, its sublicensees or their respective Affiliates discounts the purchase price of such Product to a greater degree than it generally discounts the price of its other products or services to such customer, then in such case the Net Sales for the sale of such Product to such Third Party shall equal the arm's length price that Third Parties would generally pay for the Product alone when not purchasing any other product or service from Company, its sublicensee or their respective Affiliates.

1.80 "Non-Enforcing Party" has the meaning set forth in Section 8.4.4.

1.81 "Other Halozyme Assay" has the meaning set forth in Section 5.2.2.

1.82 "Party" or "Parties" has the meaning set forth in the preamble.

1.83 "Patent Rights" means any and all patents and patent applications in the Territory (which for the purpose of this Agreement shall be deemed to include certificates of invention and applications for certificates of invention), including provisional applications, divisionals, continuations, continuations-in-part, patents-of-addition, reissues, renewals, substitutions, registrations, re-examinations, revalidations, extensions, supplementary protection certificates, or restorations by existing or future extension or restoration mechanisms, including patent term adjustments, patent term extensions, supplementary protection certificates or the equivalent thereof and the like of any such patents and patent applications, and foreign equivalents of the foregoing.

1.84 "PH20 Collaboration Inventions" has the meaning set forth in Section 8.1.2.

1.85 "PH20 Drug" means [***].

1.86 "Phase I Clinical Trial" means a human clinical trial in any country that is intended to initially evaluate the safety and/or pharmacological effect of a product in subjects or that would otherwise satisfy the requirements of 21 CFR 312.21(a), or its foreign equivalent.

1.87 "Phase II Clinical Trial" means a human clinical trial in any country that is intended to initially evaluate the effectiveness of a product for a particular indication or indications in patients with the disease or indication under study or that would otherwise satisfy the requirements of 21 CFR 312.21(b), or its foreign equivalent.

1.88 "Phase II(b) Clinical Trial Read Out Data" means the results or data obtained from a completed later stage of a Phase II Clinical Trial (such later stage intended to focus on effectiveness at specific doses.

1.89 "Phase III Clinical Trial" means a pivotal human clinical trial in any country the results of which could be used to establish safety and efficacy of a product as a basis for an NDA/BLA/MAA or foreign equivalent, or that would otherwise satisfy the requirements of 21 CFR 312.21(c), or its foreign equivalent.

1.90 "Product" means a product that consists of (a) a Company Biologic (and no other active pharmaceutical ingredients), and (b) the PH20 Drug [***].

1.91 "Receiving Party" has the meaning set forth in Section 9.1.

1.92 "Regulatory Approval" means all technical, medical and scientific licenses, registrations, regulatory inspections, authorizations and approvals (including approvals of NDA/BLA/MAAs or any foreign equivalents, supplements and amendments, pre- and post-approvals, pricing and Third Party reimbursement approvals, and labeling approvals) of any Regulatory Authority, necessary for the use, development, manufacture, and commercialization of a pharmaceutical product in a regulatory jurisdiction.

1.93 "Regulatory Approval Date" means the date on which Company receives written approval from the applicable Regulatory Authority for an NDA/BLA/MAA for a Product in the first indication in the Field.

1.94 "Regulatory Authority" means any applicable government regulatory authority involved in granting approvals for the manufacturing, marketing, reimbursement and/or pricing of a product in the Territory, including the FDA in the United States, EMA in the EU, and MHLW in Japan.

1.95 "Royalty Term" means, with respect to each Product and a given country, the period commencing with the First Commercial Sale of the applicable Product and continuing until the last to occur of (a) if the Product is Covered by a Valid Claim in such country, the end of the term for which such Valid Claim remains in effect and Covers the Product, and (b) [***] following the date of the First Commercial Sale of Product in such country.

1.96 "Selling Party" has the meaning set forth in Section 1.63.

1.97 "Target" means a unique molecular species that is (a) chemically distinct from other Biologics, compounds, or molecules, (b) a human or animal peptide, protein, or other Biologic, and (c) associated with the treatment of a human or animal disease state. For clarity, protein and peptide targets include all molecular forms generated from a specific gene with the one exception of multiple distinct hormones generated from one pro-hormone.

1.98 "Term" has the meaning set forth in Section 11.1.

1.99 "Territory" means worldwide.

1.100 "Third Party" means any person or entity other than Halozyme, Company and their respective Affiliates.

1.101 "Valid Claim" means, on a country-by-country basis, (a) a claim of an issued and unexpired patent in such country included within the Licensed Patent Rights or the Collaboration Supported Product Patents, which claim has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which claim has not been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise, or (b) a claim of a pending patent application in such country included within the Licensed Patent Rights or the Collaboration Supported Product Patents, which claim (i) was filed in good faith and (ii) has not been abandoned or finally disallowed without the possibility of appeal or refiling of such application; [***].

1.102 "Work Plan" shall have the meaning set forth in Section 5.2.3.

2. REPRESENTATIONS, WARRANTIES AND COVENANTS.

2.1 By Each Party. Each Party covenants, represents, and warrants to the other Party as follows:

2.1.1 Organization. Such Party is duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is organized.

2.1.2 Authorization and Enforcement of Obligations. Such Party (a) has the requisite power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder, (b) has taken all requisite action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder, and (c) will ensure compliance by its Affiliates [***] and sublicensees with this Agreement in connection with performance under this Agreement. This Agreement has been duly executed and delivered

on behalf of such Party, and constitutes a legal, valid and binding obligation, enforceable against such Party in accordance with its terms.

2.1.3 Consents. All necessary consents, approvals and authorizations of all governmental authorities and other persons or entities required to be obtained by such Party in connection with this Agreement have been obtained.

2.1.4 No Conflict. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (a) do not conflict with or violate any requirement of applicable laws, regulations or orders of governmental bodies; and (b) do not conflict with, or constitute a default under, any contractual obligation of such Party.

2.1.5 No Debarment. In the course of the development of each Product, neither Party shall use any employee or consultant who has been debarred by any Regulatory Authority, or, to the best of such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority.

2.2 By Halozyme. Halozyme further covenants, represents and warrants to Company as follows:

2.2.1 As of the Effective Date, Halozyme (a) exclusively owns all rights, title and interest in and to the Licensed IP Rights, and (b) has the right to grant the licenses under the Licensed IP Rights pursuant to this Agreement

2.2.2 Subject to Section 12.4, Halozyme shall not assign, license or otherwise transfer the Licensed IP Rights to a Third Party to the extent such assignment, license, or transfer would impair or adversely affect the licenses and rights granted hereunder;

2.2.3 As of the Effective Date, Exhibit A sets forth a complete and accurate list of (a) all Licensed Patent Rights existing as of the Effective Date, and (b) the owner of such Licensed Patent Rights;

2.2.4 [***];

2.2.5 Halozyme has not, prior to the Effective Date, and shall not during the Term, analyze, design around, or otherwise reverse engineer, or cause a Third Party to analyze, design around, or otherwise reverse engineer, any Company Biologic for chemical composition, or misappropriate Company's Confidential Information in order to develop a Company Biologic, biosimilar, generic, biobetter, any molecule that modulates the Company Target, or other variant, or assist any Third Party in doing any of the foregoing.

2.2.6 As of the Effective Date, (i) there are no judgments, or settlements against, or amounts with respect thereto, owed by Halozyme or any of its Affiliates relating to the Licensed Patent Rights listed on Exhibit A or the Licensed Know-How rights [***]

2.2.7 As of the Effective Date, Halozyme [***]that it or any of its designated representatives have: (a) made an untrue statement of material fact or fraudulent statement to the FDA or any other Regulatory Authority with respect to the development of the PH20 Drug, (b) failed to disclose a material fact required to be disclosed to the FDA or any other Regulatory Authority with respect to the development of the PH20 Drug, or (c) committed an act, made a statement, or failed to make a statement with respect to the development of the PH20 Drug that could reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities," set forth in 56 Fed.

Reg. 46191 (September 10, 1991) and any amendments thereto or any applicable analogous laws or policies in the Territory.

2.2.8 As of the Effective Date, Halozyme has never been the subject of a proceeding that could lead to it becoming a Debarred Entity, Excluded Entity or Convicted Entity and it will not use in any capacity under this Agreement any person who is a Debarred Individual, Excluded Individual or a Convicted Individual. Halozyme further covenants that if, during the Term, it becomes a Debarred Entity, Excluded Entity or Convicted Entity, or listed on the FDA's Disqualified/Restricted List or if any employee or agent performing any of its obligations hereunder becomes a Debarred Individual, Excluded Individual or a Convicted Individual, or added to the FDA's Disqualified/Restricted List, Halozyme shall immediately notify Company and Company shall have the right to terminate this Agreement for Halozyme's breach in accordance with Section 11.2; *provided*, however, that notwithstanding the cure period in Section 11.2, whether Halozyme is afforded an opportunity to cure such breach will be in Company's sole discretion. If Company does not allow a cure period, termination will be effective immediately. For purposes of this provision and Section 2.3, the following definitions shall apply:

(a) A "Debarred Individual" is an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from providing services in any capacity to a person that has an approved or pending drug or biological product application.

(b) A "Debarred Entity" is a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of a Debarred Entity.

(c) An "Excluded Individual" or "Excluded Entity" is (a) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services, or (b) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA).

(d) A "Convicted Individual" or "Convicted Entity" is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §335a (a) or 42 U.S.C. §1320a – 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

(e) "FDA's Disqualified/Restricted List" is the list of clinical investigators restricted from receiving investigational drugs, biologics, or devices if the FDA has determined that the investigators have repeatedly or deliberately failed to comply with regulatory requirements for studies or have submitted false information to the study sponsor or the FDA.

2.3 By Company. Company further covenants, represents and warrants to Halozyme as follows:

2.3.1 Company and its Affiliates have never been the subject of a proceeding related to it or its Affiliates becoming a Debarred Entity, Excluded Entity or Convicted Entity and it and its Affiliates will not use in any capacity under this Agreement any person who is a Debarred Individual, Excluded Individual or a Convicted Individual. Company further covenants that if, during the Term, it or its Affiliates become a Debarred Entity, Excluded Entity or Convicted Entity, or listed on the FDA's Disqualified/Restricted List or if any

employee or agent performing any of its obligations hereunder becomes a Debarred Individual, Excluded Individual or a Convicted Individual, or added to the FDA's Disqualified/Restricted List, Company shall immediately notify Halozyme and Halozyme shall have the right to terminate this Agreement for Company's breach in accordance with Section 11.2; *provided*, however, that notwithstanding the cure period in Section 11.2, whether Company is afforded an opportunity to cure such breach will be in Halozyme's sole discretion. If Halozyme does not allow a cure period, termination will be effective immediately.

2.3.2 As of the Effective Date, neither Company nor its Affiliates are conducting any research and development regarding the use of hyaluronidase as a drug delivery technology, other than any activities performed in relation to the PH20 Drug pursuant to a material transfer agreement with Halozyme, as applicable.

2.4 DISCLAIMER OF WARRANTIES. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY REPRESENTATION OR WARRANTY REGARDING VALIDITY, ENFORCEABILITY, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NONINFRINGEMENT.

3. LICENSES.

3.1 License Grants to Company.

3.1.1 Preclinical Research License.

(a) Subject to the terms and conditions of this Agreement, Halozyme hereby grants to Company a limited, non-exclusive, non-transferable (except as set forth in Section 12.4), worldwide, [***], preclinical research license under the Licensed IP Rights, solely for the purpose of conducting research and pre-clinical development of the Product, including in preclinical studies *in vitro* and *in vivo* in any non-human species in the Field. Notwithstanding the foregoing:

(i) prior to conducting any preclinical studies with respect to the Product, Company shall provide to Halozyme the study plan for Halozyme's review, and as promptly as practicable (but in any event, within [***] of receipt), Halozyme shall notify Company in writing of its approval, conditional approval (*e.g.*, subject to providing additional information, as Halozyme may reasonably request), or refusal of such plan; provided that [***]; and

(ii) Company shall not conduct any preclinical study utilizing the PH20 Drug as the sole active ingredient without the prior written consent of Halozyme, [***].

(b) Company shall not (i) use any of the data, results, analysis or conclusions resulting from the research conducted under this Section 3.1.1 to file or prosecute in any country any patent application or to support any existing patent applications (other than as provided in Article 8), or (ii) publish or publicly disclose any such data, results, analysis or conclusions resulting from the research conducted under this Section 3.1.1, in each case without the prior written consent of Halozyme; [***].

(c) Subject to the terms and conditions of this Agreement (including each Party's confidentiality and non-use obligations with respect to the Confidential Information of the other Party), nothing in this Section 3.1.1 shall preclude Halozyme from conducting

research, or negotiating, or granting any Third Party, rights to conduct research, with respect to using the PH20 Drug with respect to the Company Target.

3.1.2 Commercial License. Subject to the terms and conditions of this Agreement, Halozyme hereby grants to Company a limited, non-exclusive, non-transferable [***], worldwide license under the Licensed IP Rights, to develop, make, have made, use, offer for sale, sell and import Products in the Territory for use in the Field. [***]. Except as expressly set forth in this Agreement, Company shall not otherwise have any rights to use or license (or sublicense) the Licensed IP Rights or the PH20 Drug.

3.2 Sublicenses.

3.2.1 Company shall have the right to grant [***]

3.2.2 Any such sublicense permitted by this Section 3.2 shall: (a) be in writing, (b) include terms regarding confidentiality, inventions, and intellectual property ownership that [***], and (c) impose nondisclosure and use restrictions that are [***]; *provided*, [***] Company will provide Halozyme with a copy of any sublicense agreement promptly following its execution; *provided* [***]. Notwithstanding the foregoing, Company shall remain liable for all breaches of this Agreement by any sublicensee, shall indemnify Halozyme for Third Party claims in connection with or arising out of a sublicensee's actions or inaction, and shall remain responsible for all obligations and payments due to Halozyme hereunder.

3.3 No Implied Licenses. Only licenses and rights expressly granted herein shall be of legal force and effect. No license or other right shall be created hereunder by implication, estoppel or otherwise. [***]

3.4 No Reverse Engineering. Company has not, prior to the Effective Date, and shall not during the Term, analyze, design around, or otherwise reverse engineer, or authorize or cause a Third Party to analyze, design around, or otherwise reverse engineer, the Licensed IP Rights or PH20 Drug for chemical composition or utilize Halozyme's Confidential Information for development of a PH20 Drug biosimilar, generic, biobetter, or other variant, or otherwise assist any Third Party in doing any of the foregoing.

3.5 [***]

4. FINANCIAL TERMS.

4.1 License Fee. Company shall [***]

4.2 Milestone Payments.

4.2.1 Development Milestones. Within [***] of the first achievement by the first Product of a development milestone identified in Table 4.2.1, Company shall provide written notice of such milestone achievement to Halozyme, including the date on which each such development milestone was achieved. Within [***] following the first achievement of each of the following development milestones for any Product, Company shall pay to Halozyme the corresponding non-refundable, non-creditable, one-time milestone payment.

4.2.2 Table 4.2.1 – Development Milestone Payments

	Development Milestone	Milestone Payment (in United States Dollars, or "USD")
(a)	[***]	[***]

4.2.3

4.2.4 First Commercial Sale Milestones. Within [***] of the first achievement by the first Product of each First Commercial Sale milestone identified in Table 4.2.2, Company shall provide written notice of such milestone achievement to Halozyme, including the date on which each such First Commercial Sale milestone was achieved. Within [***] following the first achievement of each of the following First Commercial Sale milestones by a Product, Company shall pay to Halozyme the corresponding non-refundable, non-creditable, one-time milestone payment.

4.2.5 Table 4.2.2 – Commercial Milestone Payments

	First Commercial Sale Milestone	Milestone Payment (in USD)
(a)	[***]	[***]
(b)	[***]	[***]
(c)	[***]	[***]

4.2.6 Worldwide Net Sales Milestones. Following First Commercial Sale, within [***] following the end of any calendar [***] in which the annual Net Sales of Products, collectively, reach each worldwide aggregate Net Sales milestone identified in the Table 4.2.3, Company shall pay to Halozyme the corresponding non-refundable, non-creditable, one-time milestone payment. Notwithstanding the foregoing timing, Company shall use reasonable efforts to notify Halozyme of the achievement of each worldwide aggregate annual Net Sales milestone identified in the table below as promptly as possible following such achievement. For clarity, the Company Target may have multiple Products with associated sales, and therefore the sales milestones below are based on the total sales for all Products directed to the Company Target.

Table 4.2.3 – Aggregate Net Sales Milestone Payments

	Aggregate Worldwide Net Sales Milestone	Milestone Payment (in USD)
(a)	[***]	[***]
(b)	[***]	[***]
(c)	[***]	[***]

4.2.7

4.2.8 For the avoidance of doubt, (a) each of the foregoing milestone payments set forth in Sections 4.2.1 and 4.2.2 will be paid one time only for the first Product to achieve each such milestone, and no amounts shall be due for subsequent or repeated achievements of such milestone by the same Product or subsequent Products, and (b) each of the foregoing milestone payments set forth in Section 4.2.3 will be paid one time only.

4.3 Royalties. Each calendar [***] during the Royalty Term, Company shall pay to Halozyme royalties on Net Sales of Products at the below rates. [***]

Table 4.3 – Royalty Rates

Net Sales in a Calendar Year	Royalty Rate

4.4

4.4.1 As to any such Product, the royalty rate will become effective as of the [***] in which there is a First Commercial Sale of a Product in a country in the Territory, and continue in effect until the end of the applicable Royalty Term in such country.

4.4.2 For clarity, a Company Target may have multiple Products directed to the same Company Target, and therefore royalties will be calculated based on the total aggregate worldwide Net Sales for all Products directed to the Company Target.

4.4.3 Company shall pay to Halozyme royalties described in this Section 4.3 within [***] after the end of each such [***] attributable to Net Sales from Products sold during the immediately preceding calendar [***].

4.4.4 [***]

4.5 Royalty Reports; Records; Estimates; Business Reviews.

4.5.1 Each calendar [***] commencing with [***] in which there is a First Commercial Sale of a Product and ending with the last [***]in the Royalty Term, Company shall provide to Halozyme a non-binding preliminary report containing good faith estimates on worldwide Net Sales and calculation of royalties due under Section 4.3 within [***]. Company shall also provide to Halozyme the final report within [***]after the end of [***]. Such final written report shall be in the same form as the form attached hereto as Exhibit C, and will provide specific detail on a country-by-country basis.

4.5.2 With respect to amounts invoiced in United States Dollars, all such amounts shall be expressed in United States Dollars. With respect to amounts invoiced in a currency other than United States Dollars, all such amounts shall be expressed both in the currency in which the sale is invoiced and in the United States Dollar equivalent. With respect to sales of a Product incurred in a currency other than United States Dollars, such amounts and the amounts payable hereunder shall be expressed in their United States Dollar equivalent calculated using the currency rates described herein. For each calendar year during which royalties become due, Company shall provide the currency rate to be used for the local currency of each country in the Territory in which any royalty-bearing Net Sales are expected to occur based on the average of the exchange rates (local currency per US$1) published in *The Wall Street Journal*, Western Edition, under the heading “Currency Trading” on the last Business Day of October. Company shall provide currency rate details in writing no later than [***] after the currency rates are available. Each currency rate will remain constant throughout the upcoming calendar year.

Company shall use the currency rate(s) to convert Net Sales to United States Dollars for the purpose of calculating royalty payments hereunder. Company shall keep, to the extent such information is reasonably available, complete and accurate records in sufficient detail to properly reflect all Net Sales and to enable the royalties payable to be determined. All royalties payable hereunder shall be calculated based on Net Sales expressed in United States Dollars.

4.5.3 Company shall keep complete and accurate records in sufficient detail to properly reflect all gross sales and Net Sales and to enable the royalties payable to be determined.

4.5.4 No later than November 15 of each calendar year of the term, Company shall, on an annual basis, provide Halozyme with a guidance report setting out [***]. It is understood by the Parties that the guidance report provided shall be non-binding but in good faith [***], and that, notwithstanding any provision herein to the contrary, Halozyme shall not be entitled to rely on such reports or the content thereof for purposes of any claims against Company or any of its Affiliates under or with respect to the subject matter of this Agreement. [***]

4.5.5 Commencing with the first Phase III Clinical Trial for a Product, Company and Halozyme shall conduct a biannual business review to be scheduled in April and October of every year. Company shall make global Product leaders or similar qualified experts available at the time of Halozyme's biannual business review for the purposes of helping to understand actual results as well as the forecast of the current and future calendar years of Products. Such business review shall include a Company report [***].

4.6 Audits. Upon the written request of Halozyme and not more than once in a [***], Company shall permit an independent certified public accounting firm of nationally recognized standing, selected by Halozyme and reasonably acceptable to Company, to have access during normal business hours to such records of Company as may be reasonably necessary to verify the accuracy of the royalty reports hereunder for any year ending not more than [***] prior to the date of such request and that have not previously been audited. The accounting firm shall disclose to Halozyme only whether the reports are correct and the specific details of any discrepancy, but no other information shall be shared. If such accounting firm concludes that additional royalties were owed during the audited period, or that excess royalties were paid during the audited period, Company shall pay such additional royalties, or Halozyme shall provide Company with a credit for such excess royalties, as the case may be, within [***] of the date Halozyme delivers to Company such accounting firm's written report so concluding. [***]. Halozyme shall treat all financial information subject to review under this Section 4.5 as confidential, and shall cause its accounting firm to retain all such financial information in confidence.

4.7 Withholding Taxes. Company shall pay to the appropriate governmental authority on behalf of Halozyme such taxes, levies or charges that are withheld. Company shall use reasonable efforts to take such action as may be reasonably requested by Halozyme, and at Halozyme's cost, to minimize any such taxes, levies or charges required to be withheld on behalf of Halozyme by Company, *provided* that such actions do not, or could not reasonably be expected to, adversely affect or impact Company or any of its Affiliates. Company promptly shall deliver to Halozyme proof of payment of all such taxes, levies and other charges, together with copies of all communications from or with such governmental authority with respect directly related thereto. Any amounts so withheld or deducted from the payment due to Halozyme pursuant to the relevant law or regulation will be deemed paid to Halozyme for all purposes of this Agreement.

4.8 Payment Method. All payments by Company to Halozyme hereunder shall be in United States Dollars in immediately available funds (or funds that will be available on or prior to the date such payment is due) and shall be made by wire transfer to such bank account as designated from time to time by Halozyme to Company. Any payment properly due under this Agreement that is not subject to a good faith dispute which is not paid when due in accordance with the applicable provisions of this Agreement shall bear interest at an annual rate of two hundred (200) basis points above the U.S. prime lending rate (as reported in the *Wall Street Journal* (Western Edition)) or, if unavailable, such other prime rate standard as the Parties may agree in good faith, or the maximum allowable by law if less.

5. PRODUCT DEVELOPMENT AND COMMERCIALIZATION.

5.1 Alliance Program Management. Immediately following the Effective Date, each Party shall appoint alliance leads for each program associated with a Company Target. Without limitation, such program will include technical leaders from each Party for each discipline, as dictated by the then-current program needs. The alliance leader will be responsible for coordinating all business-related activities, including communication of requests and deliverables to technical leaders, who are accountable for executing technical-related activities. Each Party shall notify the other Party in writing upon making or changing its alliance leader. The alliance leader shall be the first point of contact for conflict resolution, and shall oversee the alliance program team, whose purpose shall be to (a) exchange information, (b) oversee the strategic, technical and operational aspects of the Product(s) under this Agreement, and (c) form functional working groups, as both Parties may deem appropriate. Beginning with the Effective Date, the alliance program team(s) will have quarterly meetings, unless the Parties otherwise agree on more frequent meetings. Among its responsibilities, the alliance program team shall draft and review the Work Plans and all amendments thereto; *provided*, that the Work Plans and any amendments must be executed by the Parties. Each Party shall be responsible for its own expenses in connection with the meetings of the alliance program team. Each Party (alternating from meeting to meeting) shall prepare and provide the other Party with written minutes of the alliance program team meetings within [***] after the meeting, which minutes shall be subject to the reasonable comment and written approval of the other Party, which in no event will be later than the next alliance program team meeting. For clarity, absent mutual agreement otherwise, alliance program meetings will be in addition to and not replace other meetings and/or processes referenced in this Agreement.

5.2 Responsibility.

5.2.1 Company's Right. Except as otherwise set forth in this Section 5.2, Company shall have the sole right, at its sole cost, for conducting all development, manufacture, Regulatory Approval and commercialization of Products, and shall own all clinical data, regulatory applications, filings, approvals and licenses for each Product. Notwithstanding the foregoing, Company shall not conduct any study utilizing the PH20 Drug (a) as the sole active ingredient, (b) in a placebo arm (including with saline or in any other formulation), or (c) in an arm with blood derived products, in each case, without the prior written consent of Halozyme.

5.2.2 Assays. Company may use certain bioanalytical, clinical immunogenicity and/or pharmacokinetics assays provided by Halozyme for the PH20 Drug on a stand-alone basis (each, a "Halozyme Assay") as well as certain formulation and manufacturing assays ("Other Halozyme Assays"). The bioanalytical Halozyme Assay will be available by Halozyme through its designated contract research organization ("CRO"). Company may use the bioanalytical Halozyme Assay in the research and development of the Products; *provided* that if Company believes that such Halozyme Assay will not work with a Product, then Company shall notify Halozyme and the Parties shall work together to determine an appropriate solution for the

research and development of the applicable Product. All Halozyme Assays and Other Halozyme Assays provided or made available by Halozyme shall be the sole and exclusive property of Halozyme and shall be Halozyme Confidential Information. Without limiting the foregoing or Article 9, Company may use the Halozyme Assays and Other Halozyme Assays solely for its internal research and development of Products under this Agreement (including with respect to regulatory submission requirements) and for no other purpose. Company may transfer the Other Halozyme Assays to its Affiliates, sublicensees, and Third Party CROs that are conducting research and development of Products for Company, its Affiliates, or sublicensee, pursuant to the foregoing restrictions. At reasonable cost, Halozyme shall provide to Company reference standards for use with the Other Halozyme Assays. Company shall provide Halozyme with at least [***]of lead time for preparation and supply of any required Halozyme reference standards and reagents. Halozyme will use reasonable efforts to fulfill any requests for reference standards and reagents that are less than [***] but will not be obligated to do so. Company shall provide to Halozyme all data resulting from the use of the Halozyme Assays. All data generated by or on behalf of Company with respect to such Halozyme Assays shall be owned by Company and shall be Company Confidential Information for purposes of this Agreement.

5.2.3 Work Plan. Company may engage Halozyme to conduct development and regulatory work for the PH20 Drug component of each Product and for providing technical assistance regarding the development of each Product. All such activities by Halozyme shall be conducted at the reasonable request of Company pursuant to a mutually acceptable written work plan that (a) will be in writing and signed by duly authorized representatives of each of the Parties; (b) will expressly refer to this Agreement, will form a part of this Agreement, and will be subject to the terms and conditions contained herein; and (c) will describe the specific research and development activities to be conducted by Halozyme (such work plan, as executed, the "Work Plan"). The Parties shall prepare the initial draft of the Work Plan within [***]after the Effective Date. On the [***] anniversary of the Effective Date, and each [***] period thereafter, the Parties shall meet to determine whether the Work Plan needs to be updated to reflect actual development and regulatory work being conducted (or that needs to be conducted). Halozyme shall not have any obligation to conduct any development or regulatory work that is not set forth in the Work Plan. Each [***], Halozyme shall invoice Company for the Fully Burdened Work Plan Cost to Halozyme to conduct such activities, [***], Company shall pay each such invoice within [***] after receipt.

5.2.4 Dossier. Within [***] following the Effective Date, Halozyme shall, at Halozyme's cost, provide Company with a dossier for the PH20 Drug for Company's use in Regulatory Approval filings and transfer to Company appropriate PH20 Drug-related methods and processes that are Controlled by Halozyme in order to enable Company to release Products for clinical and commercial purposes; *provided* that with respect to Halozyme Assays, Halozyme shall only provide those that are specified to be provided by Halozyme pursuant to Section 5.2.2 or are subsequently developed by Halozyme and made available to licensees of the PH20 Drug. Such dossier will include information within Halozyme's Control and regarding the PH20 Drug, including chemistry, manufacturing and controls sections and pre-clinical pharmacology and toxicology sections. Halozyme shall own any DMF for the PH20 Drug substance of each Product. If Halozyme files, holds, or controls a DMF or other regulatory registration for the PH20 Drug substance: (a) Company shall have the right to cross-reference such DMF or regulatory registration; or (b) in countries where this is not feasible, Halozyme shall provide Company, at Company's cost, with such information in Halozyme's Control regarding the PH20 Drug substance of each Product as is reasonably necessary for Company to include in the applicable Regulatory Approval filings for such Product. Halozyme shall promptly notify Company of any changes to the dossier or (if applicable) DMF or regulatory registration for the PH20 Drug substance. Company shall promptly notify Halozyme of any changes mandated or requested by any Regulatory Authority prior to making any such changes

to the dossier or (if applicable) DMF for the PH20 Drug in order to enable the Parties to agree on the appropriate changes to be made.

5.2.5 Authorizations. In addition to Section 5.2.4, Company may request Halozyme to provide authorization to regulatory agencies for Company to cross-reference appropriate regulatory filings previously made by Halozyme or its Affiliates regarding the PH20 Drug as necessary with respect to obtaining Regulatory Approval for any Product. Halozyme shall not unreasonably withhold letters of authorization.

5.3 Research and Development Reports. Company shall keep complete and accurate records of its activities conducted under Sections 5.1 and 5.2, and the results thereof. Within [***] after the end of each calendar year until the First Commercial Sale in the United States of a Product, Company shall prepare and provide Halozyme with a reasonably detailed written report of the activities conducted under this Agreement for every Product for each nominated Target, and the results thereof, through such date of such report, to develop and obtain Regulatory Approvals to market Products. Each such report shall include the projected market dynamics for each indication being pursued, including total addressable market and addressable patient population. For all Products for which a registrational trial has been initiated, prior to the start of each calendar year, Company shall provide Halozyme a written two (2) year non-binding forecast of global sales, royalties and any expected sales or development milestones, broken out into quarterly estimates.

5.4 Trademarks.

5.4.1 To the extent allowed under applicable law, Company, its sublicensee or their respective Affiliates shall have the right to determine the names and trademarks to use in connection with the promotion, marketing and sale of Products, and shall own and maintain such trademarks for use in connection with the promotion, marketing and sale of Products, other than the Licensed Marks which shall at all times remain owned by Halozyme or its Affiliates. Halozyme hereby grants Company the [***] right to use such Licensed Marks in connection with the promotion, marketing and sale of Products as secondary marks solely to indicate that the Product incorporates Halozyme technology. For clarity, nothing in this Agreement shall create an obligation on Halozyme to register or otherwise maintain in effect any Licensed Marks. Halozyme shall have the right to make reasonable use of Company's logo and Product logos on its website and ENHANZE marketing materials solely to indicate that the Product incorporates the PH20 Drug. To the extent the Company uses or displays any Licensed Mark on packaging or in other marketing or promotional materials in connection with the foregoing, Halozyme shall have the right to request samples of packaging or other marketing or promotional materials displaying the Licensed Marks to confirm compliance with Halozyme's brand usage requirements, and shall have the right to request Company make modifications in order to comply with such requirements.

5.4.2 Except as otherwise set forth above, neither Party shall, and shall ensure that its Affiliates, sublicensees, and distributors do not (a) use any of the other Party's trademarks, or any mark or name confusingly similar thereto, as part of a corporate or business name or in any other manner, or (b) register any trademark or trade name (including any company name) which is identical to or confusingly similar to or incorporates any trademark or trade name which such other Party or any associated company owns or claims rights in. Any goodwill associated with any of a Party's names or marks affixed or applied or used in connection with Products shall inure to the sole benefit of such Party. Each Party will comply with applicable laws and the current trademark usage guidelines of a Party that may be provided from time to time by the other in connection with such other Party's trademarks. Further, neither Party will modify any such marks of the other Party, nor permit any act to be done which may impair a Party's rights in or value to its trademarks. Each Party shall, upon the reasonable

request of the other Party, cooperate with the other in any action necessary or appropriate to register with the appropriate governmental agencies any Licensed Mark or Company marks for the Products, as applicable, and to protect any such mark proposed to be used.

6. REGULATORY MATTERS.

6.1 Notices. Company shall provide to Halozyme (a) advance written notice of material written communications regarding each Product (including providing copies of all filings with any Regulatory Authority) provided to a Regulatory Authority by Company; (b) a reasonable opportunity (not less than [***]) to comment on all such material written communications with respect to the PH20 Drug component of the Product prior to submission thereof taking into consideration any response deadline of the applicable Regulatory Authority (and Company shall discuss such comments with Halozyme and shall in good faith consider the reasonable comments of Halozyme with respect to the PH20 Drug component of the Product); and (c) copies of all material written communications (including all registrations and approvals) provided to Company from a Regulatory Authority regarding each Product (to be provided promptly (not to exceed [***]) following receipt thereof by Company). Company will provide a copy of the final written communications to the Regulatory Authorities to Halozyme. If any material regulatory communication will be oral or in-person, and the PH20 Drug component of a Product is scheduled to be discussed, then Company, to the extent practicable and allowed by the Regulatory Authority, will give Halozyme a reasonable opportunity to attend such oral or in-person meeting, but Halozyme will only participate with respect to the PH20 Drug component of the Product. If during any such material oral or in-person meeting that Halozyme is not attending and has not declined to attend, the PH20 Drug component of a Product arises, Company will reasonably request, as practicable, a postponement of such discussion until a Halozyme person can participate; *provided* that in no event will Company be required to postpone any discussions that would have a material effect on Company's interactions with such Regulatory Authority or Regulatory Approval of a Product.

6.2 Results. Company shall promptly, within [***], inform Halozyme in writing, in reasonably specific detail, of any material data, results or other information from a pre-clinical study or human clinical trial used (*e.g.*, registrational trial) for (a) a first registration of a Product, (b) label submission of new formulations of such Product in which either the concentration of the Company Biologic or PH20 Drug is changed or (c) label extension of such Product outside the therapeutic area of such first registration. As for all other data or results (*e.g.*, non-pivotal or non-registrational data/results) whether from a preclinical study or human clinical trial, Company shall inform Halozyme in writing of top line results within [***] of becoming aware of and finalizing such results. If Company is running a control arm in any such study or trial that involves the non-PH20 component of the Product, then Company shall also provide to Halozyme the material data, results and other information from such control arm. Company will provide to Halozyme the immunogenicity data generated on the PH20 Drug component of the Product in a format agreed upon by the Parties.

6.3 Clinical Trials. Prior to finalizing the instructional documents and protocol (or any revision thereto) for any clinical trial for a Product, (a) Company shall provide Halozyme with a copy of the reasonably complete draft of such instructional documents and protocol or revision; (b) Halozyme shall have a reasonable opportunity (not less than [***]) to review and comment on all such instructional documents and protocol or revision; (c) the Parties shall discuss Halozyme's comments relating to the PH20 Drug component of such Product; and (d) Company shall in good faith consider the reasonable comments of Halozyme relating to the PH20 Drug component of such Product. The Parties shall enter into a pharmacovigilance and safety data exchange agreement in a form acceptable to both Parties prior to the Initiation of the first clinical trial for a Product. The Parties shall conduct a joint safety review on an [***] basis,

unless the Parties mutually agree in writing that a greater (or lesser) frequency is required. Such joint safety review may either be in person or by phone, as mutually agreed.

6.4 Adverse Event Reporting. The initial pharmacovigilance and safety data exchange agreement referred to in Section 6.3 entered into by the Parties shall include provisions covering, among other things, the following concepts:

6.4.1 that each Party would promptly notify the other Party of any information that comes to such Party's attention concerning any serious adverse event drug reactions or other significant safety concerns that may lead to a change in the benefit-risk of the product associated with the clinical uses, studies, investigations, tests and marketing of the PH20 Drug or a Product. The initial pharmacovigilance agreement would define "serious" in accordance with the standards contained in applicable laws, rules and regulations, as such laws, rules and regulations may be amended, modified or replaced and detail the timelines for notification; and

6.4.2 that each Party would as soon as possible notify the other Party of any information received regarding any threatened or pending action by an agency that may affect the safety and efficacy claims of a Product and that upon receipt of any such information, the Parties would consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action; *provided* that nothing contained in the pharmacovigilance and safety data exchange agreement would restrict either Party's right to make a timely report of such matter to any government agency or take other action that it deems to be appropriate or required by applicable law, rule, regulation or court order.

6.5 Labeling. To the extent Company's proposed labeling for a Product references the PH20 Drug component, prior to filing such proposed labeling with a Regulatory Authority, (a) Company shall provide Halozyme with a copy of the proposed labeling; (b) Halozyme shall have a reasonable opportunity (not less than [***]) to review, comment and consult on the PH20 Drug component of such proposed labeling; (c) the Parties shall discuss Halozyme's comments relating to the PH20 Drug component of such labeling; and (d) Company shall in good faith consider the reasonable comments of Halozyme relating to the PH20 Drug component of such proposed labeling.

6.6 [***]

7. Clinical and Commercial Supply of API.

7.1 Manufacture and Sale. On the terms and conditions of this Article 7, Halozyme shall manufacture (or have manufactured), sell and deliver to Company all API required by Company, its sublicensees and their respective Affiliates (a) for use in the preclinical development and clinical development of the Products ("Clinical Supply") and (b) for the Products ("Commercial Supply"). Upon Company's written request, the Parties agree to negotiate in good faith to enter into a separate manufacturing and supply agreement governing the commercial supply of API for Products ("Commercial Supply Agreement"), [***]. Until such time as the Parties enter into such Commercial Supply Agreement, the terms of this Article 7 shall apply. Company shall purchase exclusively from Halozyme all quantities of API required by Company, its sublicensees and their respective Affiliates for Clinical Supply and Commercial Supply. Company shall not itself manufacture or purchase from any Third Party the PH20 Drug or any derivative, part or polymorphism (including a splice variant) of the PH20 Drug. Company shall (and shall procure that its sublicensees and their respective Affiliates shall) use such API supplied by Halozyme solely for the development, manufacture and commercialization of Products pursuant to this Agreement. [***]. Notwithstanding the foregoing, regardless of

whether Halozyme [***]provides the API under this Agreement, Company shall remain liable for [***] . [***]

7.2 Manufacturing Practices.

7.2.1 Halozyme shall manufacture, or have manufactured, API under this Article 7 in conformity with the API Specifications and in accordance with all applicable laws and regulations. [***]

7.2.2 Unless the Parties otherwise mutually agree or except as otherwise contemplated by this Agreement, Halozyme shall manufacture, or have manufactured, API under this Article 7 in accordance with cGMP.

7.2.3 Company shall have the right, at its sole expense, to audit Halozyme for compliance with applicable laws and regulations and cGMP on reasonable notice during normal business hours and not more than once in each calendar year except in the case of a for-cause audit or an audit required by applicable law, subject to reasonable confidentiality obligations. In the event the audit takes place at a CMO, Halozyme has the right to be on site during the audit and act as an observer between Company and the CMO.

7.2.4 Halozyme shall provide Company with copies of certificates of analysis for all API supplied hereunder, as reasonably requested by Company.

7.2.5 Upon the reasonable request of Company following the release and shipment of any API supplied under Article 7, Halozyme shall provide Company with relevant corresponding information, including analytical and manufacturing documentation, batch records for API supplied hereunder and stability data, in each case, requested by Company regarding quality control of such API.

7.2.6 All information disclosed or obtained pursuant to this Article 7 shall be Confidential Information of Halozyme.

7.3 API Forecasts and Orders.

7.3.1 Prior to the [***] (commencing with the first [***] in which Company, its sublicensees or their respective Affiliates order API from Halozyme hereunder), Company shall prepare and provide Halozyme with a written forecast of its good faith estimated requirements for API under this Section 7.3 for each of the subsequent [***] .

7.3.2 Company shall be required to purchase [***] of the quantity forecasted in each Binding Forecast.

7.3.3 Halozyme will be required to maintain API capacity sufficient to enable Halozyme to deliver to Company a minimum of [***] of the amounts of API set out in any Binding Forecast.

7.3.4 [***]. Halozyme shall use Commercially Reasonable Efforts to meet Company's delivery requirements specified in accordance with Section 7.3.5. [***].

7.3.5 Company shall make all purchases under this Section 7.3 by submitting firm purchase orders to Halozyme. Each such purchase order shall be in writing in a form reasonably acceptable to Halozyme, and shall specify the quantity of API ordered, the place

of delivery and the required delivery date therefor, which shall not be less than [***] after the date of such purchase order, and the API price (in accordance with Section 7.4.5). No additional terms of any such purchase order shall be binding on Halozyme unless expressly agreed to by the Parties in writing, as an amendment to this Agreement. Halozyme will notify Company of Halozyme's acceptance or rejection of any purchase order and the actual delivery date for delivery of API ordered under such purchase order no later than [***] after Halozyme's receipt of such purchase order [***]. In the event of a conflict between the terms and conditions of any purchase order and this Agreement, the terms and conditions of this Agreement shall prevail.

7.4 Delivery and Acceptance.

7.4.1 All API supplied under this Agreement shall be shipped Ex Works (EXW) (Incoterms 2020) place of manufacture or distribution to such location as designated by Company. Any change in the location of manufacture or distribution shall require the consent of Company, such consent not to be unreasonably withheld or delayed. Title and risk of loss and damages to the API purchased by Company hereunder shall pass to Company upon receipt by Company's carrier.

7.4.2 Company shall pay all freight, insurance charges, taxes, import and export duties, inspection fees, shipping validation and other charges applicable to the sale and transport of API purchased by Company under Section 7.3.5.

7.4.3 If a shipment of API or any portion thereof is not in conformance with the API Specifications when received by Company, then Company shall have the right to reject such shipment of API if the entire shipment is nonconforming, or the portion thereof that fails to so conform (in either case, "Defective API"), as the case may be. Company shall give written notice to Halozyme of its rejection hereunder within [***] after Company's receipt of such shipment, specifying the grounds for such rejection. If Company does not provide written notice of rejection during such [***], then the API shall be deemed accepted at the end of such [***] period. Notwithstanding the above, if the nonconformity of the API (a) is discovered within [***] of delivery and (b) could not reasonably have been ascertained by Company upon reasonable inspection and analysis of the API, the [***] period referred to herein shall not apply, *provided* that Company notifies Halozyme promptly within such [***] period upon discovery of such nonconformity (but in no event later than [***] from the date of the discovery). [***].

7.4.4 Company's grounds for rejection shall be conclusive unless Halozyme notifies Company within [***] of receipt by Halozyme of the notice of rejection that it disagrees with such grounds. In the event of such a notice by Halozyme, representative samples of the batch of API in question shall be submitted to a mutually acceptable independent laboratory or consultant (if not a laboratory analysis issue) for analysis or review, the costs of which shall be paid by the Party that is determined by the independent laboratory or consultant to have been incorrect in its determination of whether the applicable API should be rejected.

7.4.5 API Price. For all Clinical Supply and Commercial Supply of API supplied by Halozyme under this Agreement, Company shall pay to Halozyme a price equal to [***] . Halozyme shall invoice Company for all API upon shipment in accordance with this Article 7. Company shall pay each such invoice within [***] after receipt.

7.5 SOLE REMEDY. HALOZYME'S SOLE AND EXCLUSIVE LIABILITY TO COMPANY, AND COMPANY'S SOLE AND EXCLUSIVE REMEDY, FOR

ANY FAILURE OF THE WARRANTIES SET FORTH IN SECTION 7.6 SHALL BE, AT HALOZYME'S OPTION, [***].

7.6 Warranty. Halozyme warrants that, upon delivery, all API shall conform with the API Specifications and the certificate of analysis, shall be free from defects in manufacturing, handling, material and workmanship, and shall be manufactured in accordance with cGMP (unless the Parties otherwise mutually agree) and in compliance with applicable laws and regulations. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, HALOZYME MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO API. HALOZYME DISCLAIMS ALL OTHER WARRANTIES, EXPRESS AND IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NON-INFRINGEMENT.

7.7 Quality Agreement. The Parties agree to negotiate and enter into a mutually acceptable quality agreement relating to the supply of API hereunder within [***] after the Effective Date.

7.8 Consistency of Administration. Products developed under this Agreement shall be labeled for administration or infusion of the PH20 Drug component in such a manner so as to promote reasonably consistent use of Halozyme's PH20 hyaluronidase, [***], taking into account the need of administration for the target patient population, such labeling to be approved by Halozyme [***].

8. INTELLECTUAL PROPERTY RIGHTS.

8.1 Ownership of Intellectual Property. As between the Parties, each Party shall solely own or retain ownership of all intellectual property (including all Know-How Rights and Patent Rights) that such Party or its Affiliates: (a) Controls as of the Effective Date; or (b) discovers, creates or acquires, and Controls, during the Term outside the scope of the Agreement; and (c) except as set forth below in this Section 8.1, all improvements to any of the foregoing (collectively, with respect to each Party, such Party's "Background IP"). With respect to Collaboration Inventions, the Parties hereby agree to the following (to the extent not so provided under applicable law):

8.1.1 Company shall solely own [***] ;

8.1.2 Halozyme shall solely own [***] ; and

8.1.3 Company and Halozyme shall jointly own [***].

8.1.4 [***] .

8.1.5 Each Party shall take measures, [***], necessary for implementation of the ownership as stipulated in Sections 8.1.1 - 8.1.4, including [***].

8.1.6 [***]

8.2 Disclosure. Either Party shall promptly notify the other Party in writing of any Collaboration Inventions made, conceived or reduced to practice by or on behalf of such Party or its Affiliates.

8.3 Assignment. Each Party shall, and does hereby, assign, and shall cause its Affiliates and its and their licensees and sublicensees to assign, to the other Party, without additional compensation, such right, title, and interest in and to any Know-How Rights and proprietary intellectual property rights with respect thereto (including all rights of action and claims for damages and benefits arising due to past and present infringement of such rights) as is necessary to fully effect, as applicable, the provisions of Section 8.1 and the ownership of Collaboration Inventions and intellectual property set forth therein. [***] .

8.4 Prosecution, Maintenance and Enforcement.

8.4.1 Halozyme Prosecuted Patents.

(a) Prosecution. Halozyme shall have the exclusive right (but not the obligation), at its sole expense, to prepare, file, prosecute and maintain: [***].

(b) Enforcement. Halozyme shall have the exclusive right, at its sole expense, to enforce the Halozyme Prosecuted Patents against Third Party infringers or challengers for any infringement. With respect to any action to enforce the Halozyme Prosecuted Patents to abate any infringement by a Third Party, all monies recovered upon the final judgment or settlement of any such action shall be retained by Halozyme.

8.4.2 Company Solely-Owned Patents. Company shall have the exclusive right (but not the obligation), at its sole expense, to prepare, file, prosecute, maintain and enforce [***].

8.4.3 [***].

(a) Prosecution[***], Company shall have the first right (but not the obligation), at its sole expense, to prepare, file, prosecute, and maintain all [***].

(b) Prosecution Step-In Rights. If Company elects not to file any patent application included in the [***] in any country (whether or not a foreign equivalent of a patent or patent application in the [***] is in existence at the relevant time, and including any patent application that Halozyme, in its sole discretion, reasonably determines is included in the [***]and should be filed), or decides to abandon any such pending application or issued patent in any country (or otherwise not pursue further prosecution and maintenance of any Patent Rights that would Cover a [***], if filed), then Company shall provide sufficient written notice to Halozyme prior to the next action deadline for such patent application. Halozyme shall have the right at its sole expense to assume control of the preparation, filing, prosecution and maintenance of such patent application or patent at its own expense. Company agrees to sign such further documents and take such further actions as may be requested by Halozyme to give Halozyme authority to assume and control the foregoing preparation, filing, prosecution and maintenance. Halozyme shall give Company an opportunity to review and comment on the text of all correspondence received from and submitted to any patent office within [***] following receipt or prior to submission, as applicable. Halozyme shall consider in good faith the interests of Company in the prosecution of the [***].

(c) Enforcement. Company shall have the first right (but not the obligation) to enforce the [***] against Third Party infringers or challengers for any actual or alleged infringement at Company's sole cost and expense [***]. Company shall keep Halozyme fully informed of all developments in any such enforcement action and shall consult with Halozyme on strategy and key decisions with respect to such enforcement. Company shall have the final decision-making authority with respect to the foregoing and to settle the dispute in relation to such enforcement; *provided* that such final decisions and settlement do not diminish the rights or interests of Halozyme or admit the invalidity or unenforceability of the [***] without the prior written consent of Halozyme, such consent shall not be unreasonably withheld.

(d) Enforcement Step-In Rights. If Company fails to abate such infringement of the [***] or to file an action to abate such infringement within [***] after a written request from Halozyme to do so (or any shorter period necessary to take advantage of any legal deadlines needed to secure enhanced relief), or if Company discontinues the prosecution of any such action after filing without abating such infringement, then Halozyme shall have the right to enforce the [***] against such Third Party infringer or challenger at Halozyme' s sole cost and expense. Company agrees to sign such further documents and take such further actions as may be requested by Halozyme to give Halozyme authority to assume and control the foregoing enforcement. Halozyme shall keep Company fully informed of all developments in any such enforcement action and Halozyme shall consult with Company on strategy and key decisions with respect to such enforcement. Halozyme shall have the final decision-making authority with respect to the foregoing and to settle the dispute in relation to such enforcement; *provided* that such final decisions and settlement do not diminish the rights or interests of Company or admit the invalidity or unenforceability of the [***] without the prior written consent of Company, such consent not to be unreasonably withheld.

(e) Recovered Monies. With respect to any action to enforce the [***] to abate any infringement by a Third Party, all monies recovered upon the final judgment or settlement of any such action shall (i) first, be used to reimburse the costs and expenses (including reasonable attorneys' fees and costs) [***]; and (ii) second, be [***] . Notwithstanding the foregoing, all monies recovered upon the final judgment or settlement of any action brought, assumed or controlled by Halozyme pursuant to Section 8.4.3(d) shall be retained solely by Halozyme.

8.4.4 Cooperation. If one Party brings any suit, action or proceeding in accordance with Section 8.4.3 (such Party, the "Enforcing Party"), the other Party (the "Non-Enforcing Party") agrees to be joined as plaintiff, in each case if and only if required for the Enforcing Party to bring any such suit, action or proceeding. The Non-Enforcing Party will provide reasonable assistance to the Enforcing Party, including by providing access to relevant documents and other evidence and making its employees available. The Enforcing Party shall not enter into any settlement or compromise of any suit, action or proceeding: (a) in a manner that would diminish the rights or interests of the Non-Enforcing Party or admit the invalidity or unenforceability of any Patent Right Controlled by the Non-Enforcing Party without the written consent of the Non-Enforcing Party, which shall not be unreasonably withheld; or (b) that would impose any cost or liability on the Non-Enforcing Party, without the Non-Enforcing Party's prior written consent (which consent may be withheld at the Non-Enforcing Party's discretion).

8.5 Defense of Third Party Infringement Actions.

8.5.1 Notice. If any Product used or sold by Company, its Affiliates, or sublicensees becomes the subject of a Third Party's claim or assertion of infringement of any Patent Rights granted in the Territory, the Party first having notice of the claim or assertion shall promptly notify the other Party, the Parties shall [***].

8.5.2 Defense Rights. If a Third Party files an infringement suit alleging that the development, manufacture, production, use, importation, offer for sale, or sale of Products in the Territory infringes any Patent Rights of such Third Party, then [***].

9. CONFIDENTIALITY.

9.1 Confidentiality. With respect to any Confidential Information disclosed by a Party (the "Disclosing Party") to the other Party (the "Receiving Party") hereunder, the Receiving Party shall, and shall ensure that any of its Affiliates and Third Parties authorized to have such information, maintain in confidence the Confidential Information of the Disclosing Party and use the Disclosing Party's Confidential Information for the sole and limited purpose of fulfilling its obligations under this Agreement, in each case, during the term of this Agreement and for a period that is the longer of: (a) [***]following the expiration or earlier termination of this Agreement, and (b) in the case of Confidential Information that is a trade secret, until such Confidential Information ceases to be a trade secret. To the extent that disclosure to any person is authorized by this Agreement (*e.g.*, an Affiliate, a sublicensee, etc.) and such person has a need to know it, prior to disclosure, a Party shall obtain the written agreement of such person to hold in confidence and not disclose, use or grant the use of the Confidential Information of the other Party except as expressly permitted under this Agreement, together with other relevant terms limiting disclosure that are no less restrictive than those in this Agreement regarding disclosure and use of Confidential Information. Each Party shall notify the other Party promptly upon discovery of any unauthorized use or disclosure of the other Party's Confidential Information. As between the Parties, a Disclosing Party's Confidential Information is owned by such Party, and subject to Article 3, no license or other rights to the Disclosing Party's Confidential Information are granted or implied hereby. Notwithstanding Article 12, the Parties agree that a breach of any of the obligations in this Article 9 may result in irreparable and continuing damage to the Disclosing Party for which there is no adequate remedy at law, and the Disclosing Party may therefore seek injunctive relief and/or a decree of specific performance, in addition to such other legal and/or equitable remedies as may be available.

9.2 Exceptions. The obligations of confidentiality and non-use of a Receiving Party with respect to the Confidential Information of such Disclosing Party shall not apply with respect to any Confidential Information, to the extent that the Receiving Party can demonstrate through competent evidence that such Confidential Information:

9.2.1 is known by the Receiving Party or any of its Affiliates without an obligation of confidentiality at the time of disclosure by or on behalf of the Disclosing Party, and not through a prior disclosure by or on behalf of the Disclosing Party, as documented by the Receiving Party's business records;

9.2.2 is generally available to the public before its receipt from the Disclosing Party;

9.2.3 became generally available to the public or otherwise part of the public domain after its disclosure by the Disclosing Party and other than through any act or omission of the Receiving Party or any of its Affiliates or disclosees in breach of this Agreement;

9.2.4 is subsequently disclosed to the Receiving Party or any of its Affiliates without obligation of confidentiality by a Third Party who may rightfully do so and is not under a conflicting obligation of confidentiality to the Disclosing Party; or

9.2.5 is developed by the Receiving Party or any of its Affiliates independently and without using or referencing any Confidential Information of the Disclosing Party, as documented by the Receiving Party's contemporaneous written records.

9.3 No combination of features or disclosures will be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the Receiving Party, unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party.

9.4 Permitted Disclosures. Notwithstanding the obligations of confidentiality and non-use set forth in Section 9.1 above, a Receiving Party may provide Confidential Information disclosed to it and disclose the existence and terms and conditions of this Agreement, in each case, to the extent such disclosure is:

9.4.1 to its Affiliates, sublicensees (as permitted under this Agreement), subcontractors, consultants, and their employees, directors, agents, consultants, or advisors, in each case, to the extent necessary for the potential or actual performance of its obligations or exercise of its rights under this Agreement, in each case, who are under an obligation of confidentiality with respect to such information that is no less stringent than the terms and conditions of this Article 9; *provided* that the foregoing shall in no way be deemed to limit or supersede the obligations to implement and enforce Firewalls where required under this Agreement;

9.4.2 to the Regulatory Authorities in connection with any filing, application or request for Regulatory Approval in accordance with the terms of this Agreement; *provided* that reasonable measures shall be taken to assure confidential treatment of such Confidential Information to the extent practicable and consistent with applicable law;

9.4.3 made in connection with the prosecution or maintenance of [***]in an effort to secure, maintain, defend or enforce Patent Rights, as contemplated by this Agreement, or, with respect to such activities only, otherwise with the prior written consent of the Disclosing Party's intellectual property counsel;

9.4.4 to bring or defend litigation and to enforce Patent Rights in connection with the Receiving Party's rights and obligations pursuant to this Agreement;

9.4.5 subject to the last paragraph of this Section 9.3, required to be disclosed by applicable law, including by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange or listing entity; and

9.4.6 (a) with respect to the terms and conditions of this Agreement, any *bona fide* [***] , and (b) with respect to any other Confidential Information of the other Party, any *bona fide* [***], *provided* that any entity or individual receiving Confidential Information under clause (a) or (b) has a need to know such information and is under obligations of confidentiality and non-use with respect to such information that are no less stringent than the terms and conditions of this Article 9 (but of duration customary in confidentiality agreements entered into for a similar purpose).

9.4.7 If a Party, after consultation with counsel, determines it is required by law to disclose Confidential Information of the other Party that is subject to the confidentiality or non-disclosure provisions of Section 9.1, then such Party will promptly inform the other Party of the disclosure that is being sought (and to the extent possible at least [***]notice) in order to provide the other Party an opportunity to challenge or limit the disclosure and will reasonably cooperate with the other Party to do so. In the event that no such protective order or other

remedy is obtained, or the Disclosing Party waives compliance with certain terms of this Article 9, then the Receiving Party will furnish only that portion of Confidential Information that the Receiving Party is advised by counsel is legally required to be disclosed. Notwithstanding Section 9.1, Confidential Information that is permitted or required to be disclosed will remain otherwise subject to the confidentiality and non-use provisions of this Article 9. If either Party concludes based on the reasonable opinion of counsel that a copy of this Agreement must be filed with the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States, such Party will, within a reasonable time prior to any such filing (and to the extent possible at least [***]prior to any such filing), provide the other Party with a copy of this Agreement showing any provisions hereof as to which the Party proposes to request confidential treatment, will provide the other Party with an opportunity to comment on any such proposed redactions and to suggest additional redactions, and will take such Party's reasonable comments into consideration (and shall not unreasonably object to any such redactions) before filing such copy of this Agreement and use reasonable efforts to have terms identified by such other Party afforded confidential treatment by the applicable regulatory agency. [***].

9.4.8 Notwithstanding the foregoing, in no event shall Company disclose, or authorize the disclosure of, any Confidential Information of Halozyme or its Affiliates, or this Agreement or any terms contained herein, to any [***], without the prior written consent of Halozyme.

9.5 Publications.

9.5.1 Prior to the Regulatory Approval Date, either Party may publish the results of its research and/or development under this Agreement in order to obtain recognition within the scientific community and to advance the state of scientific knowledge, and such publication shall be subject to the following procedures. If a Party desires to make any such publication (including any oral disclosure made without obligation of confidentiality), such Party shall provide the other Party with a copy of the proposed written publication at least [***] prior to submission for publication, or an outline of such oral disclosure at least [***] prior to presentation. At the reasonable request of the other Party, the publishing Party shall remove any Confidential Information of the other Party therefrom. The other Party additionally shall have the right (a) to propose modifications to the publication for intellectual property reasons, (b) to request a reasonable delay in publication in order to protect patentable information, and (c) to propose alternative wording for scientific or clinical clarification. If the other Party requests such a delay, the publishing Party shall delay submission or presentation of the publication and shall not proceed with the written publication or the presentation without the prior written consent of the other Party, such consent not to be unreasonably withheld.

9.5.2 After the Regulatory Approval Date, Company may publish the results of its research and/or development under this Agreement in order to obtain recognition within the scientific community and to advance the state of scientific knowledge, and such publication shall be subject to the following procedures. If Company desires to make any such publication (including any oral disclosure made without obligation of confidentiality), Company shall provide Halozyme with a copy of the proposed written publication at least [***] prior to submission to a journal, or an outline of such oral disclosure at least [***] prior to presentation. At the reasonable request of Halozyme, Company shall remove any Confidential Information of Halozyme therefrom. Halozyme additionally shall have the right (a) to propose modifications to the publication for patent reasons, and (b) to request a reasonable delay in publication in order to

protect patentable information, which request Company will consider in good faith. If Halozyme requests such a delay, Company shall delay submission or presentation of the publication for a period of up to [***] to enable Halozyme to prepare and file applicable patent applications. Upon the expiration of such [***] period, subject to the requirement to remove any Confidential Information of Halozyme, Company shall be free to proceed with the written publication or the presentation, respectively, unless Halozyme has requested the delay described above.

9.5.3 Halozyme shall not publish any studies, clinical trials or results thereof regarding the [***] and only then with the prior written consent of Company. Company shall not publish any studies, clinical trials or results thereof regarding [***]. Notwithstanding any of the foregoing, the Parties agree and acknowledge that any data, information or analyses already in the public domain can be used by either Party.

9.6 Clinical Trial Registry. Company, as necessary to comply with ClinicalTrials.gov or equivalent Regulatory Authority policies and procedures, shall have the right to publish all studies, clinical trials and results thereof regarding a Product (but not the PH20 Drug alone) on the clinical trial registries which are maintained by or on behalf of Company subject to Company's compliance with Section 9.4 with respect to any proposed publication. Company shall notify Halozyme at least [***] in advance of a ClinicalTrials.gov or equivalent posting or change.

9.7 Public Announcements. On or after the Effective Date, the Parties shall issue a joint press release regarding the signing of this Agreement, the form and substance of which shall be mutually agreed to in writing by the Parties. Except (a) as set forth in the preceding sentence and (b) subject to 9.3.6 with respect to Company's reporting obligations under applicable law, rule or regulation or the rules of a stock exchange on which the securities of Company are listed, neither Party shall issue any other public announcement, press release, or other public disclosure regarding this Agreement or its subject matter without the other Party's prior written consent, except in accordance with Section 9.2.

10. INDEMNIFICATION AND INSURANCE.

10.1 By Company. Company shall indemnify and hold harmless Halozyme, its Affiliates, and their respective directors, officers, employees and agents (collectively, the "Halozyme Indemnitees"), from and against all losses, liabilities, damages and expenses, including reasonable attorneys' fees and costs (collectively, "Liabilities"), resulting from any claims, demands, actions or other proceedings by any Third Party to the extent resulting from (a) the breach of any representation, warranty, covenant, or other obligation by Company under this Agreement; (b) the use by Company, its sublicensees or their respective Affiliates of the Licensed IP Rights beyond the scope of the licenses granted herein; (c) the manufacture, use, sale, marketing, handling or storage of Products by Company, its sublicensees or their respective Affiliates, customers or end-users, including any personal injury, death or illness; (d) the use by Company, its sublicensees or their respective Affiliates of the Confidential Information of Halozyme; or (e) the gross negligence, fraud, willful misconduct or violation of applicable law by Company or its Affiliates or sublicensees; all of the foregoing except in the event and to the extent any Liability arises out of or results from (i) the negligence, fraud, willful misconduct or violation of applicable law by Halozyme or its Affiliates or (ii) matters within Halozyme's indemnification obligations under Section 10.2.

10.2 By Halozyme. Halozyme shall indemnify and hold harmless Company, its Affiliates, and their respective directors, officers, employees and agents (collectively, the "Company Indemnitees"), from and against all Liabilities resulting from any claims, demands, actions or other proceedings by any Third Party to the extent resulting from (a) the breach of any representation, warranty, covenant, or other obligation by Halozyme under this Agreement; (b)

any allegation that Company's use of the Licensed Marks in accordance with this Agreement infringes or violates the trademark rights of any Third Party; (c) the use by Halozyme, its sublicensees or their respective Affiliates of the Confidential Information of Company beyond the scope of the licenses granted herein; or (d) Halozyme's gross negligence, fraud, willful misconduct or violation of applicable law; all of the foregoing except in the event and to the extent any Liability arises out of or results from (i) the negligence, fraud, willful misconduct or violation of applicable law by Company or its Affiliates or sublicensees, or (ii) matters within Company's indemnification obligations under Section 10.1. Notwithstanding the foregoing, the indemnification obligations in this Section 10.2 do not apply to any breach by Halozyme of the warranties set forth in Section 7.6, for which Company's sole and exclusive remedy, and Halozyme's sole and exclusive liability is as specified in Section 7.5).

10.3 Procedure. If a Party (the "Indemnitee") intends to claim indemnification under this Article 10, it shall promptly notify the other Party (the "Indemnitor") in writing of any claim, demand, action or other proceeding for which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have the right to participate in, and, to the extent the Indemnitor so desires, to assume the defense thereof with counsel mutually satisfactory to the Parties; *provided*, however, that an Indemnitee shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnitor, if representation of such Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between the Indemnitee and any other party represented by such counsel in such proceeding. The obligations of this Article 10 shall not apply to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld or delayed unreasonably. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any such action, if prejudicial to its ability to defend such action, shall relieve the Indemnitor of any obligation to the Indemnitee under this Article 10. The Indemnitee, its employees and agents, shall reasonably cooperate with the Indemnitor and its legal representatives in the investigation of any claim, demand, action or other proceeding covered by this Article 10.

10.4 Insurance. Each Party shall maintain insurance, including Commercial General Liability, Product Liability and, for clinical trials it sponsors, Clinical Trials Liability insurance, Workers Compensation and Employer's Liability and Errors and Omissions Liability insurance, with respect to its activities under this Agreement regarding Products in such amount as such Party customarily maintains with respect to similar activities for its other products, but not less than the greater of (a) [***] each occurrence and aggregate for Commercial General Liability, Product Liability, and Clinical Trials Liability insurance in amounts compliant with local insurance regulations and [***] limit per accident /disease and a $500,000 disease policy limit Workers Compensation and Employer's Liability and Errors and Omissions Liability or (b) such amount as is reasonable and customary in the industry. Each Party shall maintain such insurance for so long as it continues its activities under this Agreement, and thereafter for [***]. Upon written request, each Party shall provide the other Party with written evidence of the required coverage. Each Party shall provide the other Party [***] notice of any material change, cancellation or non-renewal of any required insurance under this Agreement. In the event of a material change, cancellation, or non-renewal in coverage, each Party shall replace such coverage to comply with this Agreement so that there is no lapse of coverage for any time period.

11. TERM AND TERMINATION.

11.1 Term. This Agreement shall commence on the Effective Date and, unless earlier terminated pursuant to this Section 11, shall continue until the expiration of the last Royalty Term in the Territory for such Product (the "Term").

11.2 Termination for Material Breach. If a Party believes that the other Party has materially breached this Agreement, the non-breaching Party may deliver written notice of such material breach to the other Party. If such material breach is curable, (a) the breaching Party will have [***] following its receipt of such written notice of material breach to cure such material breach and (b) if the breaching Party fails to cure such material breach within such [***] period, then the non-breaching Party shall have the right to terminate this Agreement by providing written notice of termination to the breaching Party, in which case, this Agreement will terminate on the date on which the breaching Party receives such written notice of termination. If such material breach is not curable, the Agreement will terminate [***] following the date on which the breaching Party receives such written notice of material breach. Notwithstanding the foregoing, in the event that the allegedly breaching Party disputes whether a material breach as occurred, or whether any alleged material breach is curable or cured, in each case during the [***] period referred to above, then the allegedly breaching Party will promptly refer such matter for resolution in accordance with the expedited dispute resolution process set forth in Section 12.2, this Agreement will not be terminated as a result of such alleged breach during the pendency of such dispute.

11.3 Termination.

11.3.1 For Convenience. Subject to Section 11.4.1, Company may terminate this Agreement for convenience by providing Halozyme with [***] advance written notice of termination.

11.3.2 [***]. Halozyme may terminate this Agreement upon notice to Company in the event of [***].

11.4 Effect of Expiration or Termination.

11.4.1 Expiration or termination of this Agreement shall be without prejudice to any rights that have accrued to the benefit of a Party prior to such expiration or termination. Upon expiration or termination of this Agreement, all licenses granted by either Party hereunder (and any sublicenses to any Affiliate or Third Party) shall terminate automatically as of the termination or expiration effective date; *provided* that in the event of any termination by Halozyme or termination by the Company for convenience pursuant to Section 11.3.1, Company and its Affiliates will not, directly or indirectly, and will not license, engage, or otherwise authorize any Third Party to on its or their behalf, [***]. Without limiting the foregoing, Sections 1, 2.4, 3.3, 4.2 (as to payment obligations that have accrued prior to the effective date of expiration or termination of this Agreement, or pursuant to Section 11.4.2), 4.3 (as to payment obligations that have accrued prior to the effective date of expiration or termination of this Agreement, or pursuant to Section 11.4.2), 4.4, 4.5, 4.6 (for a period of [***] after expiration or termination of this Agreement), 4.7 (as to payment obligations that have accrued prior to the effective date of expiration or termination of this Agreement, or pursuant to Section 11.4.2), 6.1, 6.4, 7.6, 7.7, 8, 9 (for the applicable period included in clauses (i) and (ii) of Section 9.1), 10.1, 10.2, 10.3, 11.5, and 12 shall survive any expiration or termination of this Agreement. The Parties acknowledge that the past, present and future exchange of valuable assets and support (including intellectual property (such as Know-How Rights), Confidential Information (and ongoing protection thereof), supply of API, facilitation of Product development, and the like) provide consideration sufficient to support the rights and obligations under the Agreement, including any surviving obligations of the Parties set forth in this Section 11.4.1.

11.4.2 Following termination of this Agreement [***], Company and its Affiliates and sublicensees will have the right to continue to sell off their existing inventories of

Products for a period not to exceed [***] after the effective date of such termination, *provided* that [***].

11.4.3 Except as otherwise expressly set forth in this Agreement, promptly upon the expiration or earlier termination of this Agreement, each Party shall return to the other Party all tangible items regarding the Confidential Information of the other Party and all copies thereof and delete all electronic data and files provided under this Agreement and all copies thereof from such Party's computer systems and electronic data storage devices; *provided*, however, that each Party shall have the right to retain (a) any Confidential Information that such Party is required to retain by any applicable laws, rules and regulations, including laws and regulations providing for a duty to preserve documents for a civil lawsuit in accordance with such laws, rules and regulations, (b) digital backup files automatically generated by such Party's customary electronic data processing system so long as such retention is properly stored as confidential files for the sole purpose of backup and is deleted in accordance with such Party's retention policy, and (c) one (1) copy for its legal files for the sole purpose of determining its obligations hereunder.

11.5 Section 365(n) of the Bankruptcy Code.

11.5.1 All rights and licenses granted under or pursuant to any section of this Agreement are, and shall otherwise be deemed to be, for purposes of section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. Upon the filing or institution of bankruptcy, reorganization, liquidation, or receivership proceedings, upon the appointment of a receiver or trustee over all or substantially all property, or upon an assignment of a substantial portion of the assets for the benefit of creditors by Halozyme, Halozyme agrees that Company, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. Each Party acknowledges and agrees that "embodiments" of intellectual property within the meaning of Section 365(n) include laboratory notebooks and research studies and data. If (i) a case under the U.S. Bankruptcy Code is commenced by or against Halozyme, (ii) this Agreement is rejected as provided in the U.S. Bankruptcy Code, and (iii) Company elects to retain its rights hereunder as provided in Section 365(n) of the U.S. Bankruptcy Code (which, for avoidance of doubt, shall be as such rights existed immediately before the commencement of such case, and solely for the duration of the Term), then Halozyme (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) will, upon written request of Company:

11.5.2 (a) provide Company with a copy of all such intellectual property (including all embodiments thereof, to the extent protected by applicable non-bankruptcy law) held by Halozyme and such successors and assigns to the extent included in or comprising the Licensed IP Rights, immediately upon Company's written request; and

11.5.3 (b) not interfere with Company's rights under this Agreement, or any agreement supplemental hereto, to such intellectual property (including such embodiments), including any right to obtains such intellectual property (or such embodiments) from another entity, to the extent provided in Section 365(n) of the U.S. Bankruptcy Code.

In such event, the royalty payments shall be deemed "royalties" as defined under Section 365(n) of the U.S. Bankruptcy Code.

11.5.4 All rights, powers, and remedies of Company provided in this Section 11.5 are in addition to and not in substitution for any other rights, powers, and remedies

now or hereafter existing at law or in equity (including the U.S. Bankruptcy Code) in the event of the commencement of a case under the U.S. Bankruptcy Code with respect to Halozyme.

12. MISCELLANEOUS.

12.1 Governing Law; Escalation; Arbitration. This Agreement shall be governed in all respects by the laws of the State of New York, without regard to the conflicts of law principles thereof. The United Nations Convention of International Contracts on the Sale of Goods (the Vienna Convention) does not apply to this Agreement. If there is a dispute between the Parties under this Agreement that cannot be resolved by the alliance leaders, then the dispute shall be referred to a member of executive management to be designated by each Party for resolution. If the executives cannot resolve such matter within a period of [***] from the date on which such matter is referred to them, either Party may invoke the dispute resolution process herein. Except with respect to any action, suit or proceeding seeking specific performance or injunctive or interim, provisional or precautionary measures or other equitable relief, each Party agrees that any controversy or claim in any way arising out of or relating to this Agreement shall be determined by a panel of three (3) arbitrators in an arbitration administered by the International Centre for Dispute Resolution (hereinafter "ICDR" or the "Arbitration Center"), in accordance with its International Arbitration Rules in force at the time of the submission. Each Party shall have the right to select one (1) arbitrator, and the selected arbitrators shall select (by unanimous agreement) the third arbitrator; *provided*, that all arbitrators must have substantial experience adjudicating disputes relating to pharmacology and intellectual property licensing, and may (but need not be) from among the members of the arbitration body of the Arbitration Center. Prior to the appointment of the arbitrators, each Party may veto up to two (2) arbitrators proposed by the other Party or by the selected arbitrators without cause. The arbitrators are specifically empowered to resolve any matter related to their competence and/or jurisdiction. The place of the arbitration shall be in [***]. For all legal purposes, the Parties agree [***] and agree that the arbitration shall be governed by the laws of the [***]. Judgment upon any award(s) rendered in such arbitration will be binding. The Parties hereto irrevocably submit to the exclusive jurisdiction of any federal or state court located within the [***] for enforcement of or challenge to any such award(s) rendered by an arbitrator pursuant to this Section, and each Party hereby irrevocably agrees that all claims in respect of such dispute, any suit, action, or proceeding related thereto, or any other action, suit or proceeding seeking specific performance or injunctive or interim, provisional or precautionary measures or other equitable relief, may, in each case, be heard and determined in such courts. The Parties hereby irrevocably waive, to the fullest extent permitted by applicable law, any objection which they may now or hereafter have to the laying of venue or any such dispute brought in such court or any defense of inconvenient forum for the maintenance of such dispute. The arbitrators' award shall include a determination of the prevailing Party's reasonable legal fees and costs associated with any such arbitration to be reimbursed by the non-prevailing Party. To the extent any arbitration award is brought before a court for enforcement purposes, the Parties will waive trial by jury in any such proceeding. The Parties undertake to keep confidential all awards in their arbitration, together with all materials in the proceedings created for the purpose of the arbitration and all other documents produced by another Party in the proceedings not otherwise in the public domain, except and to the extent that disclosure may be required of a Party by applicable law or to enforce or challenge an award in legal proceedings before a court or other judicial authority, in which case the Party disclosing such information shall, to the extent permissible under applicable law, give the other Party reasonable advance notice of such disclosure and use reasonable efforts to secure confidential treatment of such information (whether through protective order or otherwise).

12.2 Expedited Arbitration. In the event of any dispute as to whether a material breach of this Agreement has occurred or whether a material breach is curable or has been cured, the Parties will submit to an expedited binding arbitration to resolve the dispute, which will be determined by arbitration administered by ICDR in accordance with its International Expedited

Procedures. The place of the expedited arbitration shall be in [***]. For all legal purposes, the Parties agree that the arbitration shall be governed by the laws of the [***]. The Parties grant special irrevocable power of attorney to the ICDR, so that, in accordance with the ICDR's standard list selection process, it may appoint the arbitrator from among the members of the arbitration body of the Arbitration Center that have sufficient experience adjudicating similar disputes relating to intellectual property licensing in connection with pharmaceutical and biological products.

12.3 Waivers. The failure of any Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party.

12.4 Assignment. Neither this Agreement nor any right or obligation hereunder may be assigned or delegated, in whole or part, by either Party without the prior written consent of the other; except that either Party may assign this Agreement and its rights and obligations hereunder without the consent of the other Party, but with prompt notice of such assignment, to: (a) such Party's Affiliate(s) (except with respect to Third Parties that become an Acquirer pursuant to a Change of Control, which is solely addressed in the following subsection (b) below), *provided* that, as between the Parties, such Party shall remain primarily liable for any acts or omissions of such Affiliate; (b) the Acquirer in connection with a Change of Control, or otherwise under a transaction under which this Agreement is assumed, or the successor or acquiring party in connection with a sale of all or substantially all of the assets of such Party or to which this Agreement relates (in which case, such Party shall assign this Agreement to such successor or acquiring party in connection with such sale of assets). Notwithstanding the foregoing, in no event shall Company assign this Agreement or its rights or obligations hereunder, in whole or in part, to [***]. Any Acquirer or permitted assignee shall assume all obligations of its assignor under this Agreement, and Company shall cause such Acquirer or permitted assignee to agree in writing to such assumption and to be bound by, and fully perform, the terms and conditions of this Agreement. Any purported assignment in violation of this Section 12.4 shall be void.

12.5 Change of Control.

12.5.1 12.5.1 Company shall provide Halozyme written notice of any Change of Control of Company promptly, but no later than [***], following the earlier of the first public announcement of such Change of Control or the execution of a definitive agreement relating to such Change of Control (if such disclosure is not prohibited under applicable law or by the terms of any written agreement between Company and any Third Party), which notice shall describe in reasonable detail the nature of the transaction and the identity of the Acquirer. If, as of the closing date of such Change of Control transaction, such Acquirer is a [***], then the following shall apply: (a) Company shall implement or cause its Acquirer to [***], and (b) Company shall continue to comply with its obligations under this Agreement in full force and effect, or shall cause such Acquirer to comply with such obligations (if applicable, to the extent Acquirer succeeds Company).

12.5.2 Halozyme shall have the right, through a designated Third Party auditor reasonably acceptable to Company, to audit Company's (and, as applicable, its Affiliates') Firewall obligations under this Agreement for purposes of confirming compliance with the Firewalls, identifying any vulnerabilities or breaches and requiring Company (or its Affiliates) to promptly remediate any non-compliance identified by such audit. In connection

with such audit, duly authorized representatives of Halozyme's designated auditor may make an on-site visit to Company (or its Affiliate) for the purpose of conducting such audit. Halozyme may conduct such audits from time to time as reasonably necessary to confirm Company's compliance with such Firewall requirements no more than once per calendar year or more frequently if Halozyme reasonably believes at any time that Company is not in compliance with such Firewall requirements; *provided* that if the auditor identifies a breach of the Firewall, Halozyme will be entitled to an additional audit within the same year to verify that appropriate action has been taken to remedy the breach of the Firewall. If the auditor identifies any breach of the Firewall, Halozyme and/or the auditor will notify Company, and Company will promptly (and will use reasonable efforts to ensure its Affiliates promptly) take all action necessary to remedy such breach, and will provide Halozyme with reasonable assurance that such action has been taken, at Company's sole expense.

12.6 Independent Contractors. The relationship of the Parties hereto is that of independent contractors. The Parties hereto are not deemed to be agents, partners or joint venturers of the other for any purpose as a result of this Agreement or the transactions contemplated thereby.

12.7 Further Actions. Each Party shall execute, acknowledge and deliver such further documents and instruments and perform all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

12.8 Notices. Any and all notices or other communications or deliveries required or permitted to be provided hereunder must be in writing, and in English, and will be deemed given and effective only if: (a) delivered by hand or by overnight courier with tracking capabilities; (b) mailed postage prepaid by first class, registered, or certified mail; or (c) delivered by electronic mail followed by delivery via either of the methods set forth in clauses (a) and (b) of this Section (which such notice shall be deemed effective on the date of delivery of the electronic mail, provided the delivery of the additional notice via either of the methods set forth in clauses (a) and (b) of this Section occurs reasonably promptly following the electronic mail delivery), in each case, addressed as set forth below unless changed by notice so given:

If to Halozyme: Halozyme, Inc.
12390 El Camino Real
San Diego, California 92130
Attn: [***]
Email: [***]

If to Company: Skye Bioscience, Inc.
11250 El Camino Real
San Diego, California 92130
Attn: [***]
Emai: [***]

With a copy to:

11250 El Camino Real
San Diego, California 92130
Attn: [***]
Emai: [***]

12.9 Force Majeure. Delay or, if delay is not appropriate under the circumstances, nonperformance of a Party (in either case, other than for the payment of money) shall be excused to the extent that performance is rendered impossible by pandemic, strike, fire, earthquake, flood, governmental acts or orders or restrictions, acts of terrorism, failure of suppliers, or any other reason where failure to perform is beyond the reasonable control and not caused by the negligence, intentional conduct or misconduct of the nonperforming Party; *provided* that the nonperforming Party shall use Commercially Reasonable Efforts to resume performance as soon as reasonably practicable.

12.10 No Consequential Damages. IN NO EVENT SHALL A PARTY BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 12.10 WILL LIMIT OR RESTRICT, AND THE FOREGOING LIMITATIONS SHALL NOT APPLY TO, THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY UNDER ARTICLE 10 OR LIMIT EITHER PARTY'S LIABILITY FOR (A) A BREACH OF ARTICLE 9 (CONFIDENTIALITY) OR (B) SUCH PARTY'S (OR ITS AFFILIATE'S) GROSS NEGLIGENCE, FRAUD OR WILLFUL MISCONDUCT.

12.11 Complete Agreement; Amendments. This Agreement, together with the Schedules and Exhibits hereto, constitute the entire agreement between the Parties regarding the subject matter hereof, and all prior representations, understandings and agreements regarding the subject matter hereof, either written or oral, expressed or implied, are superseded and shall be of no effect. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.

12.12 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed to be an original and together shall be deemed to be one and the same agreement.

12.13 Interpretation. The headings to the several sections hereof are not a part of this Agreement, but are included merely for convenience of reference only and shall not affect its

meaning or interpretation. Unless specified to the contrary, references to Sections, Schedules or Exhibits mean the particular Sections, Schedules or Exhibits to this Agreement and references to this Agreement include all Exhibits hereto. In the event of any conflict between the main body of this Agreement and any Exhibit hereto, the main body of this Agreement shall prevail. Unless context otherwise clearly requires, whenever used in this Agreement: (a) the words "include" or "including" shall be construed as incorporating, also, "but not limited to" or "without limitation"; (b) the word "day" or "year" means a calendar day or year unless otherwise specified; (c) the word "notice" means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement; (d) the words "hereof," "herein," "hereby" and derivative or similar words refer to this Agreement as a whole and not merely to the particular provision in which such words appear; (e) the words "shall" and "will" have interchangeable meanings for purposes of this Agreement; (f) provisions that require that a Party, the Parties or a committee hereunder "agree," "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise; (g) words of any gender include the other gender; (h) words using the singular or plural also include the plural or singular, respectively; (i) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then current amendments thereto or any replacement law, rule or regulation thereof; (j) references to "dollars", "$" or other references to currency shall mean U.S. Dollars, unless otherwise stated; and (k) neither Party shall be deemed to be acting on behalf of the other Party.

12.14 Severability. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use reasonable efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the Parties hereto have each caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

HALOZYME, INC.

By: /s/ Cortney Caudill

Name: Cortney Caudill

Title: Chief Operating Officer

Skye Bioscience, Inc.

By: /s/ Punit Dhillon

Name: Punit Dhillon

Title: CEO

[Signature Page to Non-Exclusive Collaboration and License Agreement]

SCHEDULE 1.5

API Specifications

[***]

EXHIBIT A

Licensed Patent Rights

[***]

EXHIBIT B

[***]

EXHIBIT C

Form of Royalty Report

[***]

SKYE BIOSCIENCE, INC.
CODE OF BUSINESS CONDUCT AND ETHICS

I. Policy Statement

It is the policy of Skye Bioscience, Inc. (together with its subsidiaries, the "Company") to conduct its affairs in accordance with all applicable laws, rules, and regulations of the countries in which it does business. This Code of Business Conduct and Ethics (this "Code") applies to the Company's employees, officers, and directors (collectively, the "Company Personnel"). This Code also applies to certain independent contractors, consultants, and advisors who work at the Company's facilities or on the Company's behalf, in which case those persons will be notified and provided with a copy of this Code. Such persons will be deemed Company Personnel for purposes of this Code.

This Code is designed to deter wrongdoing and to promote:

- honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;
- full, fair, accurate, timely, and understandable disclosure in the reports and documents the Company files with, or submits to, the Securities and Exchange Commission ("SEC") and in other public communications made by the Company;
- compliance with applicable governmental laws, rules, and regulations;
- ethical, transparent, and appropriate interactions with healthcare providers, patients, and other third parties and appropriate communication with third parties about Company products and the diseases and medical conditions for which they are being studied or are approved to treat;
- the protection of the Company's assets, including corporate opportunities and confidential information;
- fair dealing practices;
- the prompt reporting to the appropriate person or persons of violations or alleged violations of this Code; and
- accountability for adherence to this Code.

The Company has established standards for behavior that affect the Company, and Company Personnel must comply with those standards. The Company promotes ethical behavior and encourages Company Personnel to talk to supervisors, managers, the General Counsel or Chief Financial Officer, or other appropriate personnel when in doubt about the best course of action in a particular situation. Anyone aware of a situation that he or she believes may violate or lead to a violation of this Code should follow the guidelines under "Compliance and Reporting" below.

This Code covers a wide range of business practices and procedures. It does not cover every issue that may arise, but it sets out basic principles to guide all Company Personnel. Specific policies and procedures of the Company provide details pertinent to many of the provisions of this Code. Company Personnel are required to be familiar with, and to act in accordance with, this Code, the Company's Employee Handbook, and the Company's other policies and procedures, as may be adopted from time to time. Where the proper course of action is unclear, do not hesitate to use the resources available whenever it is necessary to seek clarification.

II. Compliance and Reporting

A. Compliance

Any Company Personnel who violate the provisions of this Code may be subject to disciplinary action, up to and including termination or removal from office. The Company will not tolerate the violation of laws and regulations applicable to its business and underlying this Code. Such violations by Company Personnel will be dealt with swiftly and may require the Company to refer such violation(s) for criminal prosecution or civil action.

B. Reporting Procedures and Other Inquiries

Questions regarding this Code or the Company's policies and procedures may be directed to managers or supervisors, the General Counsel or the Chief Financial Officer. The Nominating and Corporate Governance Committee of the Company's Board of Directors (the "Committee") shall identify an appropriate individual in the event these functions are unable to perform the compliance functions covered in this Code. Managers and supervisors shall provide timely advice and guidance to Company Personnel on ethics and compliance concerns and are expected to take a leadership role in promoting ethical business conduct.

Any Company Personnel having knowledge of, or questions or concerns about, an actual or possible violation of the provisions of this Code involving directors, executive officers, or the General Counsel are expected to promptly report the matter to the General Counsel (or to the Company's Chief Executive Officer (the "CEO") if the matter involves the General Counsel) who will promptly share the facts about the actual or possible violation of the provisions of this Code with the Chairman of the Committee (or to the other members of the Committee if the matter involves the Chairman of the Committee). Any Company Personnel having knowledge of, or questions or concerns about, an actual or possible violation of the provisions of this Code involving anyone other than a director, executive officer, or the General Counsel are expected to promptly report the matter to their immediate supervisor, or a member of management of the Company or Human Resources Department, which report will then be promptly shared with the General Counsel and the Chief Financial Officer.

In addition, Company Personnel may submit reports of actual or possible violations of the provisions of this Code, and concerns and information regarding this Code, through the following options, which may be submitted on an anonymous basis:

- **Telephone:**

English speaking USA and Canada: 844-280-0005

Spanish speaking USA and Canada: 800-216-1288

Spanish speaking Mexico: 01-800-681-5340

French speaking Canada: 855-725-0002

- **Website:** https://www.lighthouse-services.com/skyebioscience
- **E-mail:** reports@lighthouse-services.com (must include company name with report

When submitting a report, Company Personnel are asked to provide as much detailed information as possible. Providing detailed, rather than general, information will greatly assist the Company in effectively investigating complaints. This is particularly important where a person submits a report on an anonymous basis.

The Company supports, and has taken efforts to foster, a "speak up" culture and is providing anonymous reporting procedures so that Company Personnel may disclose genuine concerns without feeling threatened. The Company prohibits any retaliation or retribution against any Company Personnel who in good faith submits a report under this Code. The Company will keep confidential to the extent permissible under applicable law, and consistent with an effective investigation, all communications with a reporting individual relating to the individual's report.

All reports of an alleged prohibited action made under this Code in good faith will be taken seriously. After receiving a report of an actual or possible violation of the provisions of this Code, the Committee (if the report involves directors, executive officers, or the General Counsel) or the General Counsel (if the report involves anyone other than a director, executive officer, or the General Counsel) must promptly take all appropriate actions necessary to investigate. Company Personnel are expected to cooperate in any such investigation.

If, after investigating a report of an alleged prohibited action by a director, executive officer, or the General Counsel, the Committee determines that a violation of this Code has occurred, the Committee will report such determination to the full Board of Directors. Upon receipt of a determination that there has been a violation of this Code, the Board of Directors (with respect to directors, executive officers, or the General Counsel) or the General Counsel (with respect to anyone other than a director, executive officer, or the General Counsel) will take such preventative or disciplinary action deemed appropriate, including, but not limited to, reassignment, demotion, dismissal and, in the event of criminal conduct or other serious violations of the law, notification of appropriate governmental authorities.

Company Personnel who file reports or provide evidence that they know to be false or without a reasonable belief in the truth and accuracy of such information will not be protected by this Code and may be subject to corrective action, up to and including immediate termination or removal from office.

For the avoidance of doubt, nothing in this Code is to be interpreted or applied in any way that prohibits, restricts or interferes with any Company Personnel's (a) exercise of rights provided under, or participation in, "whistleblower" programs of the SEC or any other applicable regulatory agency or governmental entity (each, a "Government Body"), or (b) good faith reporting of possible violations of applicable law to any Government Body, including cooperating with a Government Body in any governmental investigation regarding possible violations of applicable law.

III. Waivers; Amendments; Interpretation

Each of the Committee (in the case of a violation of this Code by a director, executive officer, or the General Counsel) and the General Counsel (in the case of a violation of this Code by any other person) may, in its discretion, waive any violation of this Code. Any waiver for a director or an executive officer shall be disclosed as and to the extent required by SEC and Nasdaq rules.

Other than technical, administrative, or other non-substantive amendments, changes in this Code may only be made by the Board of Directors and must be promptly disclosed as and to the extent required by SEC rules. In some situations, it may not be clear whether a provision of this Code is

intended to apply to particular conduct. In such situations, the Committee has full power and authority to interpret the Code in a manner that its members believe reflects the intent of the Board of Directors, and no determination that this Code was not intended to apply to such conduct shall be deemed to be a waiver of this Code's prohibitions.

IV. Conflicts of Interest

A conflict of interest arises when an individual's personal or outside business interests (or the interests of a member of their family) interferes, or even appears to interfere, with their ability to act or make decisions in the best interests of the Company. Company Personnel must discharge their responsibilities on the basis of what is in the best interest of the Company independent of personal considerations or relationships. Non-employee directors must discharge their fiduciary duties as directors of the Company.

Company Personnel other than directors and executive officers who have questions about potential conflicts of interest or who become aware of an actual or potential conflict of interest should discuss the matter with their supervisor or a member of the Human Resources Department. A supervisor or a member of the Human Resources Department may not authorize or approve conflict of interest matters or make determinations as to whether a problematic conflict of interest exists without first providing the General Counsel (or the CFO if the actual or potential conflict of interest matter concerns the General Counsel) with a written description of the activity and seeking the General Counsel's (or CFO's, if applicable) written approval. Company Personnel must disclose potential conflicts of interest involving their spouse, siblings, parents, in-laws, children and other family members or members of their household (related party transactions). The General Counsel (or CFO, if applicable) shall review and approve or disapprove of the related party transaction. In doing so, the General Counsel (or CFO, if applicable) shall review the material facts and will take into account, among other factors, whether the related party transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related party's interest in the related party transaction.

Directors and executive officers must seek determinations and prior authorizations or approvals of potential conflicts of interest exclusively from the Audit Committee of the Board of Directors, in accordance with the Company's Related Party Transactions Policy.

V. Business Relationships and Fair Dealing

The Company seeks to outperform its competition fairly and honestly. The Company seeks competitive advantages through superior performance, not unethical or illegal business practices. Company Personnel must deal fairly with the Company's customers, suppliers, competitors, employees, and anyone else with whom they have contact in the course of performing their job and must not take advantage of them through manipulation, concealment, abuse of privileged information, misrepresentation of material facts, or any unfair-dealing practice.

VI. Fair Competition

Fair competition laws, including U.S. antitrust rules and regulations, limit what the Company can do with another company and what the Company can do on its own. Generally, the laws are designed to prohibit agreements or actions that reduce competition and harm consumers. Company Personnel may not enter into agreements or discussions with competitors that have the effect of fixing

or controlling prices, dividing, and allocating markets or territories, or boycotting suppliers or customers. U.S. and foreign antitrust rules and regulations also apply to imports and exports.

VII. Interactions With Healthcare Professionals

The Company interacts with healthcare professionals ("HCPs") on a regular basis. All interactions with HCPs are intended to benefit patients and to enhance the practice of medicine. This can include advancing medical research, enhancing medical knowledge, or gathering necessary feedback about the Company's products. The Company never provides gifts or entertainment to HCPs, and it does not provide anything of value, to induce or reward favorable decisions about its products.

The Company occasionally contracts with HCPs to provide services to the Company, but only when the Company has a legitimate business need for the services. These contracts for service are never a disguised way of inducing HCPs to prescribe, purchase, or recommend the Company's products or of rewarding them for doing so. Compensation for HCPs' services is always consistent with the fair market value of the services provided.

VIII. Gifts, Gratuities, Entertainment and Other Considerations

Use of Company funds or other Company property for illegal, unethical, or otherwise improper purposes is prohibited. The purpose of business entertainment and gifts in a commercial setting is to create goodwill and a sound working relationship, not to gain personal advantage with customers or suppliers. Gifts and entertainment may not be provided to HCPs.

A. Loans

Employees may not accept loans from any person or entities having or seeking business with the Company. Loans by the Company to, or guarantees by the Company of obligations of, employees or their family members are of special concern and could constitute improper personal benefits to the recipients of such loans or guarantees, depending on the facts and circumstances. Executive officers and directors (or their family members) may not receive loans from the Company, nor may the Company arrange for any such loan.

B. Bribes and Kickbacks

The use of Company funds, facilities, or property for any illegal or unethical purpose is strictly prohibited.

- Company Personnel are not permitted to offer, authorize, give, or cause others to give, any payments or anything of value for the purpose of influencing the recipient's business judgment or conduct in dealing with the Company.
- Company Personnel may not solicit or accept a kickback or bribe, in any form, for any reason. Items of value that may be construed as a bribe or improper payment may include money, promises of goods or services, gratuities, commissions, or fees that are disproportionate to the services provided, lavish or excessive entertainment, hospitality, or gifts, and charitable or political contributions.
- No gift or entertainment should ever be offered, given, provided, or accepted by any Company Personnel or their family members, unless it: (1) is not a cash gift, (2) is consistent with customary business practices, (3) is reasonable in value, (4) cannot

be construed as a bribe or payoff, and (5) does not violate any laws, regulations, or applicable policies of the other party's organization. Company Personnel should seek guidance in accordance with this Code if they are not certain whether any gifts or proposed gifts are appropriate.

- In addition to these expectations with respect to all dealings on behalf of the Company, Company Personnel must never offer, pay, or provide, directly or indirectly, anything of value to a third-party as an inducement to prescribe, purchase, or recommend a Company product or as a reward for having done so.
- The Company cannot undertake through a third-party intermediary any act that the Company itself is not permitted to do.

IX. Doing Business Internationally

The Company is committed to the highest business conduct standards wherever it operates. The Company observes these standards worldwide, even at the risk of losing business. While no one can anticipate all the situations that may present challenges to Company Personnel doing business in the worldwide marketplace, the following guidelines always apply:

- Observe all laws and regulations, both U.S. and non-U.S., that apply to business abroad.
- Paying bribes to government officials is absolutely prohibited, even if those bribes are common practice. You may not give, promise to give or authorize the giving to a foreign official, a foreign political party, or official thereof or any candidate for foreign political office any money or offer, gift, promise to give or authorize the giving of anything of value to influence any act or decision, to induce such official, party or candidate to do or omit to do any act in violation of the lawful duty of such official, party, or candidate, or to induce such official, party, or candidate to use their influence with a foreign government or agency to affect or influence any act or decision of such foreign government or agency. Company Personnel must conduct all dealings on behalf of the Company in compliance with applicable laws and regulations, including without limitation the federal Anti-Kickback Statute, the U.S. Foreign Corrupt Practices Act, the UK Bribery Act, and applicable state and international anti-bribery and anti-kickback statutes.
- Do not cooperate with illegal boycotts.
- Observe all licensing requirements and the requirements of applicable import and export control laws.

The laws governing the Company's business in foreign countries are extensive and complex and may be different from those in the United States. Company Personnel should ensure that they are familiar with the Company's policies and procedures for conducting business outside of the United States. Any questions regarding conducting business in foreign countries should be directed to the General Counsel.

X. Data Privacy & Use of Protected Health Information

The Company is committed to complying with the evolving standards governing data privacy and it is the Company's policy to appropriately protect the confidentiality of personally identifiable data as well as protected health information and only use this data to the limited extent needed for its business. The Company appropriately limits access to this data, and always endeavors to comply with applicable laws and regulations. Questions about data privacy or how to handle protected health information or personal financial information should be directed to the General Counsel.

XI. Political Contributions and Lobbying

No political contributions are to be made using the Company's funds or assets to any political party, political campaign, political candidate, or public official in the United States or any foreign country, unless the contribution is lawful and expressly authorized. In addition, Company Personnel may not make a political contribution on behalf of the Company, or with the appearance that such contribution is being made on behalf of the Company, unless expressly authorized. A "contribution" is any direct or indirect payment, distribution, loan, advance, deposit, or gift of money, services, or anything of value in connection with an election or to an organization or group formed to support or defend a referendum or ballot issue.

Company Personnel must obtain approval of the General Counsel to hire outside counsel or a public affairs firm to contact government officials regarding legislation, regulatory policy, or rule making. This includes grassroots lobbying contacts.

XII. Accuracy of Reports, Records and Accounts

Company Personnel are responsible for the accuracy of their records, time sheets, and reports. Accurate information is essential to the Company's ability to meet legal and regulatory obligations and to compete effectively. The records and books of accounts of the Company must meet the highest standards and accurately reflect the true nature of the transactions they record. Destruction of any records, books of account or other documents except in accordance with the Company's document retention policy is strictly prohibited.

Company Personnel must not create false or misleading documents or accounting, financial or electronic records for any purpose relating to the Company, and no one may direct an employee to do so. For example, expense reports must accurately document expenses actually incurred in accordance with the Company's policies. Company Personnel must not obtain or create "false" invoices or other misleading documentation or invent or use fictitious entities, sales, purchases, services, loans, or other financial arrangements for any purpose relating to the Company. Company Personnel are also responsible for accurately reporting time worked.

No undisclosed or unrecorded account or fund may be established for any purpose. No false or misleading entries may be made in the Company's books or records for any reason. No disbursement of corporate funds or other corporate property may be made without adequate supporting documentation or for any purpose other than as described in such documentation. Company Personnel must comply with generally accepted accounting principles, the Company's internal controls, and the Company's policies and procedures governing retention, storage, retrieval and handling of the Company's documents and records.

XIII. Litigation and Government Investigations

Company Personnel must promptly notify the General Counsel of any potential litigation with any other party, or government investigation or inquiries from government agencies concerning the Company. Company Personnel may not destroy any records, books of account, or other documents relating to the Company except in accordance with the Company's document retention policy. Company Personnel that are aware of litigation or potential litigation with a third party or a government investigation or inquiry, may not destroy or delete any records, books of account, or other documents relating to the Company

unless advised by the General Counsel that they may continue to follow the Company's normal document retention policy.

Company Personnel must not obstruct the collection of information, data, or records relating to the Company. The Company provides information to the government that it is entitled to during an inspection, investigation, or request for information. Company Personnel must not lie to government investigators or make misleading statements in any investigation relating to the Company. Company Personnel must not attempt to cause other Company Personnel to fail to provide accurate information to government investigators.

XIV. Insider Trading

Company Personnel who have access to material non-public information are not permitted to use such information for their personal benefit or the benefit of others or share that information for stock trading purposes or for any other purpose, except to conduct the Company's business.

Inside information is material information about a publicly traded company that is not known by the public. Information is deemed "material" if it could affect the market price of a security or if a reasonable investor would attach importance to the information in deciding whether to buy, sell, or hold a security or vote a particular way on a matter up for a vote. Inside information often relates to financial conditions, such as progress toward achieving revenue and earnings targets or projections of future earnings or losses of the Company. To the extent material and nonpublic, inside information also includes changes in strategy, a proposed merger, acquisition or tender offer, new products or services, regulatory filing status, contract awards, and clinical trial information and results. Inside information is not limited to information about the Company. It also includes material non-public information about others, including the Company's customers, suppliers, and competitors.

Insider trading is prohibited by law. It occurs when an individual with material, non-public information trades securities or communicates such information to others who trade. The person who trades while in possession of material, non-public information, or who "tips" information for others to trade violates this Code and the law.

Trading or helping others trade while aware of inside information has potential serious legal consequences, even if the insider does not receive any personal financial benefit. Insiders may also have an obligation to take appropriate steps to prevent insider trading by others.

For more information, please refer to the Company's Insider Trading Policy.

XV. Confidentiality

One of the Company's most important assets is its confidential information. Company Personnel may learn of information about the Company that is confidential and proprietary. Company Personnel who have received or have access to confidential information must keep this information confidential, except when disclosure is expressly authorized or is required or permitted by law. Confidential information includes non-public information that might be of use to competitors or harmful to the Company or its customers if disclosed, such as business plans, scientific and technical strategies, financial information, information related to the Company's research, clinical trials and results, inventions, works of authorship, trade secrets, processes, conceptions, formulas, patents, patent applications, licenses, suppliers, manufacturers, customers, market data, personnel data, personally identifiable information pertaining to the Company's employees, customers, or other individuals (including, for example, names, addresses, telephone numbers and social security numbers), and similar types of information provided to the

Company by its customers, suppliers and partners. This information may be protected by patent, trademark, copyright, and trade secret laws.

In addition, because the Company interacts with other companies and organizations, there may be times when Company Personnel learn confidential information about other companies. Company Personnel must treat this information in the same manner as they are required to treat the Company's confidential and proprietary information. There may even be times when Company Personnel must treat as confidential the fact that the Company has an interest in, or is involved with, another company.

Company Personnel must keep confidential and proprietary information about the Company, or any other company, learned in the course of employment or involvement with the Company confidential unless and until that information is released to the public through approved channels (usually through a press release or an SEC filing). In addition, Company Personnel must refrain from discussing confidential or proprietary information with other Company Personnel, unless they have a legitimate need to know the information in order to perform their job duties. Unauthorized use or distribution of this information could also be illegal and result in civil liability and/or criminal penalties.

Company Personnel must take care not to inadvertently disclose confidential information. Materials that contain confidential information, such as memos, notebooks, and laptop computers, should be stored securely. Unauthorized posting or discussion of any information concerning the Company's business, information, or prospects on the Internet is prohibited. Company Personnel may not discuss the Company's business, information, or prospects on any social media platform, regardless of whether they use their own name or a pseudonym, without prior authorization from the CEO or CFO. Social media broadly includes online platforms that facilitate activities such as professional or social networking, posting commentary or opinions and sharing pictures, audio, video, or other content such as personal websites and all types of online communities (e.g., Facebook, LinkedIn, Yelp, YouTube, X, Instagram, blogs, message boards, and chat rooms). Be cautious when discussing sensitive information in public places like elevators, airports, restaurants and "quasi-public" areas in and around the Company's place of business. All Company emails, voicemails, and other communications are presumed confidential and should not be forwarded or otherwise disseminated outside of the Company except where required for legitimate business purposes.

XVI. Protection and Proper Use of Company Assets

All Company Personnel are expected to protect the Company's assets and ensure their efficient use. Theft, carelessness, and waste have a direct impact on the Company's profitability. The Company's property, such as office supplies, computer equipment, and offices, are expected to be used only for legitimate business purposes, although incidental personal use may be permitted. Company Personnel may not, however, use the Company's corporate name, any brand name or trademark owned or associated with the Company or any letterhead stationery for any personal purpose.

Company Personnel may not, while acting on behalf of the Company or while using the Company's computing or communications equipment or facilities, either:

- access the internal computer system (also known as "hacking") or other resource of another entity without express written authorization from the entity responsible for operating that resource; or
- commit any unlawful or illegal act, including harassment, libel, fraud, sending of unsolicited bulk email (also known as "spam") or material of objectionable content

in violation of applicable law, trafficking in contraband of any kind, or any kind of espionage.

If Company Personnel receive authorization to access another entity's internal computer system or other resource, they must make a permanent record of that authorization so that it may be retrieved for future reference, and Company Personnel may not exceed the scope of that authorization. Unsolicited bulk email is regulated by law in a number of jurisdictions. If Company Personnel intend to send unsolicited bulk email to persons outside of the Company, either while acting on the Company's behalf or using its computing or communications equipment or facilities, they must contact their supervisor or the General Counsel for prior approval.

All data residing on or transmitted through the Company's computing and communications facilities, including email and word processing documents, is the property of the Company and subject to inspection, retention, and review by the Company, with or without Company Personnel's or third party's knowledge, consent, or approval, in accordance with applicable law. Any misuse or suspected misuse of the Company's assets must be immediately reported to the General Counsel.

The obligation of Company Personnel to protect the Company's assets includes the Company's proprietary information. Proprietary information includes intellectual property such as trade secrets, patents, trademarks, and copyrights, as well as business, marketing and service plans, engineering and manufacturing ideas, designs, databases, records, and any unpublished financial data and reports.

Unauthorized use or distribution of this information is a violation of Company policy. It could also be illegal and result in civil or criminal penalties.

Company Personnel are prohibited from taking for themselves personally (or for the benefit of friends or family members) opportunities that are discovered through the use of corporate property, information, or position without approval. Without approval, Company Personnel may not use the Company's property or information, or their position with the Company, for improper personal gain. Company Personnel may not compete with the Company, directly or indirectly, except with the prior written permission of the General Counsel.

XVII. Media/Public Discussion

It is the Company's policy to disclose material information concerning the Company to the public only through specific limited channels to avoid inappropriate publicity and to ensure that all those with an interest in the company will have equal access to information. All inquiries or calls from the press and financial analysts should be referred to the Company's Chief Executive Officer ("CEO") or CFO, or communications personnel as designated by the CEO or CFO. The Company has designated the CEO and CFO as the Company's official spokespersons for financial matters and scientific, clinical, technical, and other related information. Unless a specific exception has been made by the CEO , he or she is the only person who may communicate with the press on behalf of the Company. Company Personnel may not provide any information to the media about the Company off the record, for background, confidentially, or secretly.

XVIII. Environmental

All Company Personnel must fully comply with all applicable laws relating to the protection of the environment in the conduct of the Company's business. Company Personnel must use, store, and dispose of all hazardous materials properly and in accordance with applicable regulations. Company

Personnel must report, in accordance with Company policies, all circumstances under which hazardous materials or waste come in contact with the environment, are improperly handled or disposed of, or where a potential violation of law may exist.

XIX. Public Reporting

Full, fair, accurate, timely, and understandable disclosure must be made in the reports and other documents that the Company files with, or submits to, the SEC and in its other public communications. Such disclosure is critical to ensure that the Company maintains its good reputation, complies with its obligations under the securities laws and meets the expectations of its stockholders.

Persons responsible for the preparation of such documents and reports and other public communications must exercise the highest standard of care in accordance with the following guidelines:

- all accounting records, and the reports produced from such records, must comply with all applicable laws;
- all accounting records must fairly and accurately reflect the transactions or occurrences to which they relate;
- all accounting records must fairly and accurately reflect in reasonable detail the Company's assets, liabilities, revenues, and expenses;
- accounting records must not contain any false or intentionally misleading entries;
- transactions must not be intentionally misclassified as to accounts, departments, or accounting periods;
- all transactions must be supported by accurate documentation in reasonable detail and recorded in the proper account and in the proper accounting period;
- no information may be concealed from the internal auditors or the independent auditors; and
- compliance with the Company's internal controls over financial reporting and disclosure controls and procedures is required.

This Code is not an employment contract between the Company and its employees, nor does it modify their employment relationship with the Company.

This Code is intended to clarify Company Personnel's obligations for proper conduct. The standards and the supporting policies and procedures may change from time to time in the Company's discretion. Company Personnel must comply, both in letter and spirit, with all applicable laws, rules, regulations, standards, policies, and procedures in the cities, states, and countries in which the Company operates. Company Personnel are not expected to know the details of all applicable laws, rules, regulations, standards, policies, and procedures but need to know enough to determine when to seek advice from appropriate personnel. Company Personnel who have questions about applicable laws, rules, regulations, standards, policies, and procedures should contact the General Counsel. To the extent that provisions of local law are more restrictive than this Code, Company Personnel are to follow the more restrictive provisions. To the extent any provision of this Code is expressly prohibited by the laws of a particular jurisdiction in which the Company does business, the laws of that

jurisdiction will prevail within that jurisdiction. The most current version of this Code can be found at www.skyebioscience.com.

Subsidiaries of the Registrant

Name of Entity	Formation Date	Jurisdiction of Incorporation	Holder of Stock
Nemus	July 17, 2012	California, USA	Skye Bioscience, Inc.
Skye Bioscience Pty Ltd.	August 9, 2019	Australia	Skye Bioscience, Inc.
Emerald Health Therapeutics, Inc.	July 31, 2007	British Columbia, Canada	Skye Bioscience, Inc.
Bird Rock Bio Sub, Inc.	November 16, 2006	Delaware, USA	Skye Bioscience, Inc.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-3 (Registration Nos. 333-258243, 333-279330, and 333-279331) and Form S-8 (Nos. 333-223439, 333-226259, 333-227860, 333-245177, 333-276211, 333-281460, 333-281461, 333-283068, and 333-285957) of our report dated March 10, 2026, with respect to the consolidated financial statements of Skye Bioscience, Inc. and Subsidiaries included in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ CBIZ CPAs P.C.

Morristown, New Jersey
March 10, 2026

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-3 (Registration Nos. 333-258243, 333-279330, and 333-279331) and Form S-8 (Nos. 333-223439, 333-226259, 333-227860, 333-245177, 333-276211, 333-281460, 333-281461, 333-283068, and 333-285957) of our report dated March 20, 2025, with respect to the audit of the consolidated financial statements of Skye Bioscience, Inc. and Subsidiaries for the year ended December 31, 2024, included in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ Marcum LLP

Morristown, New Jersey
March 10, 2026

EXHIBIT 31.1

Certification of Principal Executive Officer
Required By Rule 13a-14(A) of the Securities Exchange Act of 1934, As Amended,
As Adopted Pursuant To Section 302 of the Sarbanes--Oxley Act of 2002

I, Punit Dhillon, certify that:

1. I have reviewed this annual report on Form 10-K of Skye Bioscience, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Ru1es 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Ru1es 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particu1arly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2026

/s/ Punit Dhillon
Punit Dhillon, Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

Certification of Principal Financial and Accounting Officer
Required By Rule 13a-14(A) of the Securities Exchange Act of 1934, As Amended,
As Adopted Pursuant To Section 302 of the Sarbanes--Oxley Act of 2002

I, Punit Dhillon, certify that:

1. I have reviewed this annual report on Form 10-K of Skye Bioscience, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Ru1es 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Ru1es 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particu1arly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2026

/s/ Punit Dhillon
Punit Dhillon, Chief Executive Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

Certification of Principal Executive Officer
Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of Skye Bioscience, Inc., a Nevada corporation (the "Company") on Form 10-K for the year ending December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Punit Dhillon, Chief Executive Officer of the Company, hereby certify, that, to my knowledge, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

A signed original of this written statement required by Section 906 has been provided to Skye Bioscience, Inc., and will be retained by Skye Bioscience, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

/s/ Punit Dhillon

Punit Dhillon
Chief Executive Officer
(Principal Executive Officer)

March 10, 2026

EXHIBIT 32.2

Certification of Principal Financial and Accounting Officer
Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of Skye Bioscience, Inc., a Nevada corporation (the "Company") on Form 10-K for the year ending December 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Punit Dhillon, Chief Executive Officer of the Company, hereby certify, that, to my knowledge, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

A signed original of this written statement required by Section 906 has been provided to Skye Bioscience, Inc., and will be retained by Skye Bioscience, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

/s/ Punit Dhillon

Punit Dhillon
Chief Executive Officer
(Principal Financial and Accounting Officer)

March 10, 2026