**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, 2024

☐ **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 $224,823,935 as of June 30, 2024, based upon the closing price of $8.01 per share of the registrant's common stock on the Nasdaq Global Market on June 30, 2024, the last business day of the registrant's most recently completed second fiscal quarter.

As of March 19, 2025, there were 30,974,558 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 2025 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, 2024.

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**PART I**

**Forward-Looking Statements**

This Annual Report on Form 10-K for the year ended December 31, 2024 (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 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;
- 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 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.

We are conducting CBeyond™, a Phase 2a proof-of-concept trial of nimacimab administered as a subcutaneous injectable for the treatment of obesity and overweight in the United States. The CBeyond™ study is also assessing the combination of nimacimab and a GLP-1 receptor agonist. We anticipate providing a top-line readout from the CBeyond™ study late in the third quarter or early in the fourth quarter of 2025, enabling a comprehensive view of nimacimab’s safety and efficacy profile.

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

### Strategy

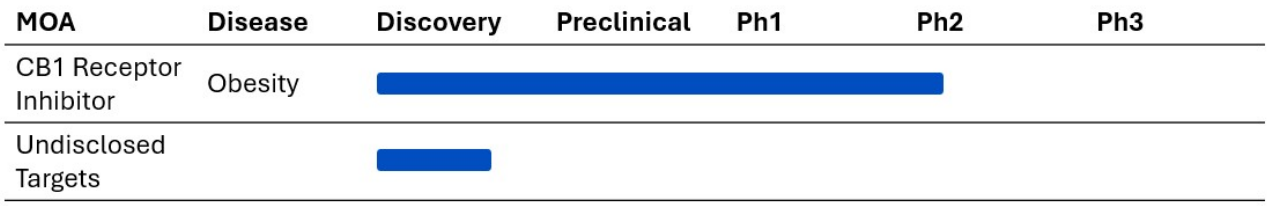
Beyond nimacimab, our strategy is to develop and implement proprietary methods and platform technologies aimed at advancing a broad, scalable, and combinable portfolio of GPCR-based therapeutics to treat obesity, overweight and related conditions. Our goal is to address not only the limitations of approved therapies, but also many of the anticipated challenges posed by next-generation treatments. Through this anticipated future pipeline, we will remain committed to transforming metabolic health and delivering breakthrough treatments for high-burden, life-threatening conditions.

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 first-in-class therapies that meet significant unmet medical needs globally.

Key elements of our strategy include:

- Advancing nimacimab through clinical development with an initial focus on completing the CBeyond Phase 2a study for the treatment of patients with obesity and overweight and evaluating its potential as a standalone, second-line or combination 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.

The status of our development pipeline is as follows:




**Our Product Candidate**

*Nimacimab*

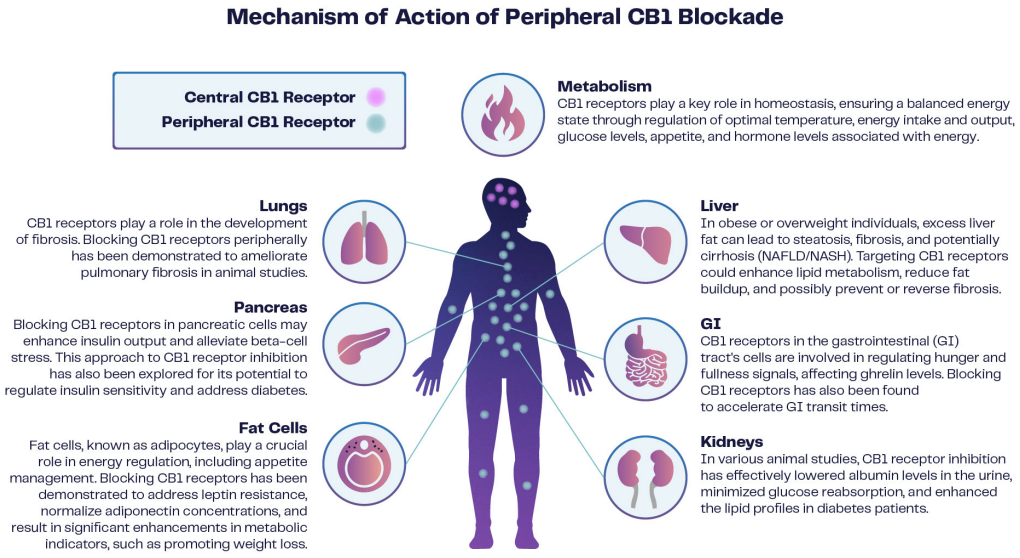
We completed the acquisition of Bird Rock Bio, Inc. (“Bird Rock”), a privately held, clinical-stage biotechnology company, in August 2023. Through this transaction, we acquired nimacimab, a humanized IgG4 negative allosteric modulating ("NAM") antibody that specifically binds to the CB1 receptor with no cross-reactivity to other GPCRs, including cannabinoid receptor 2 ("CB2"). Nimacimab was originally evaluated in a Phase 1 clinical study for nonalcoholic fatty liver disease related to a different development strategy. We are now conducting a Phase 2a proof-of-concept trial of nimacimab in people with overweight and obesity and expect to report a top-line readout late in the third quarter or early in the fourth quarter of 2025. To obtain 52 weeks of treatment data, the CBeyond trial will be extended to provide a longer-term assessment of safety, tolerability and efficacy. The protocol extension will provide for continued assessment of both the nimacimab monotherapy (primary endpoint) and the nimacimab/GLP-1 combination cohort (exploratory endpoint).These results will represent the first in-human clinical data for nimacimab in the treatment of obesity.

*Unmet Need and Market Opportunity*

Global obesity rates have been rising dramatically, affecting more than one billion people worldwide (approximately 650 million adults). Obesity and overweight are complex diseases characterized by excess and chronic inflammation of adipose tissues, and it results from a chronic energy surplus in which the body's energy intake exceeds its energy expenditure. 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. 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. Previous treatments for obesity have been limited by safety concerns and insufficient efficacy, which we believe hindered their success. However, incretin-based therapeutics has shown significant weight loss and positive cardiovascular effects in clinical studies. GLP-1 receptor agonists ("GLP-1") have been effective in reducing overall body weight, but 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 with incretin therapies like GLP-1s could improve outcomes compared to solely using GLP-1 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 primarily 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 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. 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 achieving further peripheral restriction. Small molecule-based 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 and may achieve similar or more favorable efficacy than other therapies in 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 and diarrhea, which can lead to discontinuation of treatment in some cases.

We believe nimacimab stands apart from GLP-1's 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*

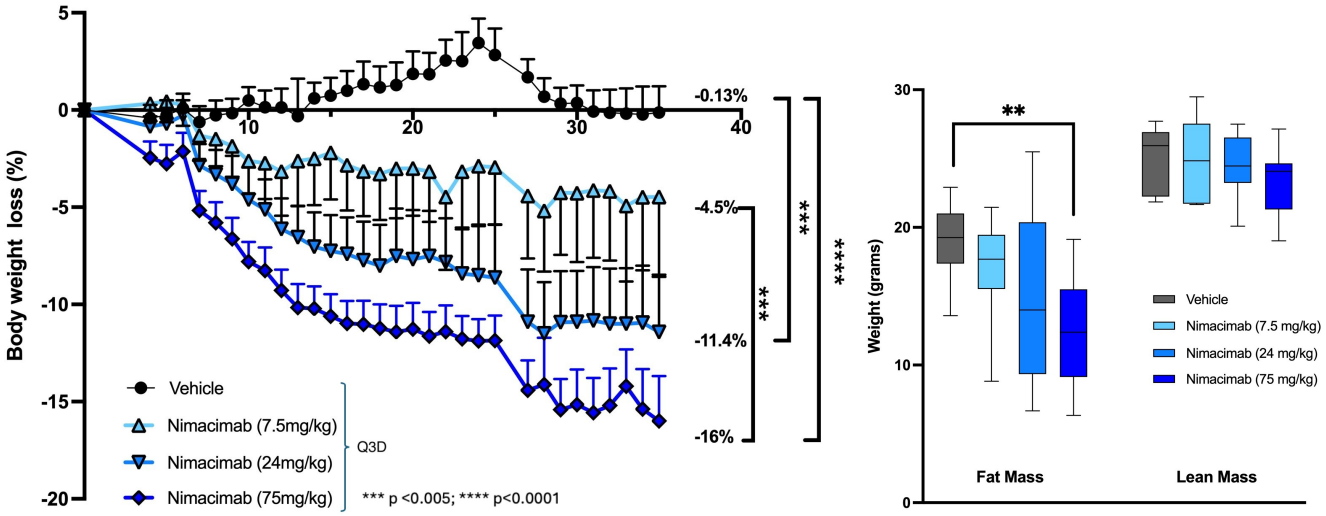
Within the CB1 inhibitor class, we believe nimacimab is distinct from competing drug candidates primarily because it is a large-molecule antibody, and has a distinct mechanism of noncompetitive inhibition that collectively confers several advantages over the small molecules in development.

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 study 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). 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. This can become critical as CB1 signaling is often overactive in metabolic diseases, and direct competition with an inverse agonist 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 Pharmacokinetic ("PK") 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 reduced 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.

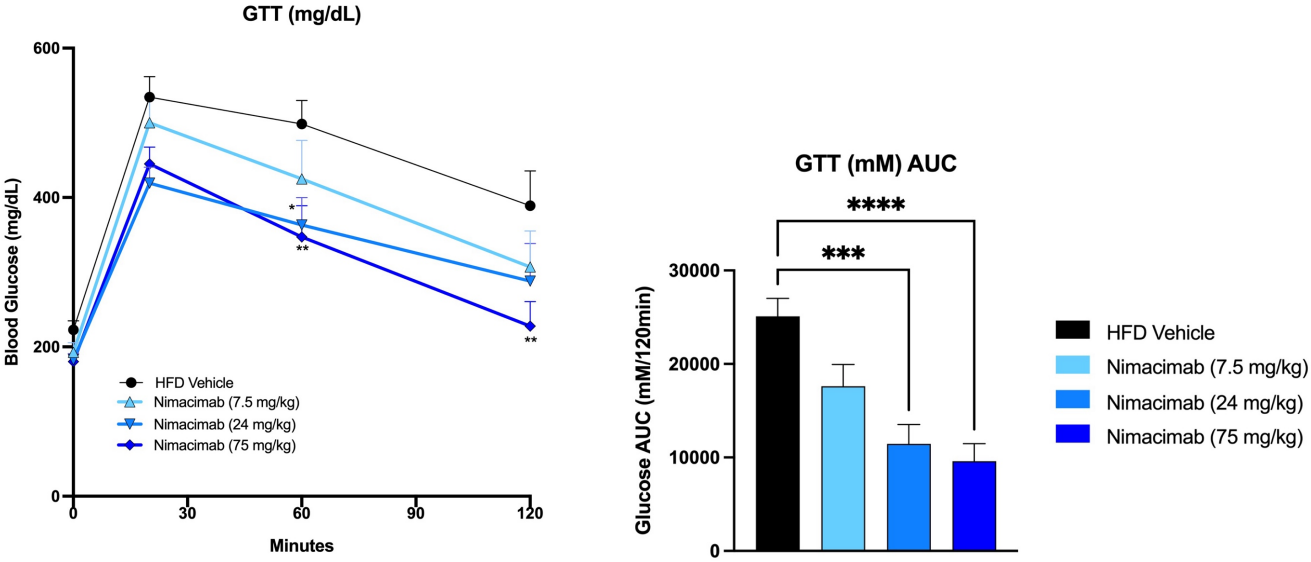
*Preclinical Data*

The CB1 pathway is clinically validated and has many supporting studies that highlight peripheral mechanisms to promote productive metabolic changes, including weight loss. However, sufficiency of nimacimab-driven weight loss and related metabolic gains remained a critical hurdle to be addressed. Outside of clinical studies, 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"). 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 improvement in glucose tolerance.




The above figure highlights body weight and composition analyses performed with two-way analysis of variance ("ANOVA") repeated measurements. A Tukey multiple comparison test was then performed for all pairwise comparisons. Body weight reporting occurred at day 35 of treatment and body composition was measured with an echoMRI on day 33.




Beyond weight loss and productive body composition, the above data demonstrates positive changes in glycemic control with a dose-dependent improvement in glucose tolerance in obese mice. Day 27 mice fasted for four hours before receiving an intraperitoneal injection of 10 grams of glucose with measurement of blood glucose over 120 minutes as part of the glucose tolerance test ("GTT"). GTT analyses included (1) a two-way ANOVA repeated measurements (a Tukey multiple comparison test) and (2) a baseline subtracted area under the curve ("AUC") analysis performed with a one-way ANOVA with a Tukey multiple comparison test.

In addition to clinical data sets from monlunabant and rimonabant, this DIO data supports 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. Instead, this data suggest that central CB1 inhibition may only minimally contribute to efficacy, yet is likely to be a driver of neuropsychiatric adverse events.

*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. 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 Data*

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 fatty liver disease ("MAFLD"). 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 NAFLD. 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 NAFLD 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 overall low immunogenicity.

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.

We believe the preliminary trends seen in the Phase 1 study, over a short duration of treatment, demonstrated the potential for nimacimab to have similar or greater effects on modulation of weight and treating conditions known to be associated with obesity.

*Clinical Development Plan*

In August 2024, we initiated a 26 week Phase 2a proof-of-concept trial with a 13 week follow up, CBeyond™ for nimacimab in obesity. The CBeyond™ clinical trial recruited approximately 136 evaluable patients in 16 clinical trial sites to assess differences in weight loss, body composition, and other attributes. This CBeyond™ clinical trial's primary endpoint is to evaluate weight loss using nimacimab compared to placebo. Secondary endpoints include evaluations of safety and tolerability, neuropsychiatric and cognitive evaluation, change in body composition by Dual-Energy X-ray Absorptiometry ("DEXA"), and changes in key metabolic biomarkers such as triglycerides, and insulin and leptin sensitivity. Patients will also be recruited to an exploratory combination arm with a GLP-1 agonist. To obtain 52 weeks of treatment data, the Company is planning a trial extension that increases the originally planned 26 weeks of treatment to provide a longer-term assessment of safety, tolerability and efficacy. The protocol extension will provide for continued assessment for all four treatment arms including both the nimacimab monotherapy (primary endpoint) and the nimacimab/GLP-1 combination cohort (exploratory endpoint).

**Competition**

The biopharmaceutical industry is intensely competitive and is 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.

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.

**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.

**Intellectual Property**

The success of most 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 19, 2025, we owned three granted U.S. patents, 38 granted foreign patents, including granted patents in Europe, Japan, Korea and China, as well as other commercially relevant jurisdictions, and 16 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 an international (PCT) patent application 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 application 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. 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.

A combination product candidate with a biologic primary mode of action, as we expect our combination products to be regulated, generally would be reviewed and approved pursuant to a BLA. 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, CMS, an agency within the DHHS, 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, or 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 19, 2025, we have a total of 16 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 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 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 on Form 10-K and our other filings with the Securities and Exchange Commission, or the SEC, before making an investment decision regarding our common stock.

- We are dependent on third parties to manufacture nimacimab.
- We have a limited operating history, a history of losses and expect to incur additional losses in the future.
- We will require substantial additional financing to achieve our goals.
- We depend heavily on the ability to advance nimacimab through clinical development.
- 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 equityholders, 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 $26,567,123 and $37,644,784 for the years ended December 31, 2024 and December 31, 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $130,949,672. 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.

***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:

- successful completion 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 Phase 2a clinical trial of nimacimab 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.

We believe that our existing cash, cash equivalents and investment securities will enable us to fund our operations for at least the next 12 months from the date of this Annual Report on Form 10-K. In particular, we expect these funds will allow us to complete our ongoing Phase 2a study for nimacimab and manufacturing activities for our Phase 2b study for nimacimab in obesity. However, we do not expect these funds will be sufficient to complete our Phase 2b study for nimacimab or manufacturing activities necessary to supply a Phase 3 clinical study or enable us to complete the clinical trials needed to seek marketing approval or commercialize nimacimab or any future product candidates. 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. 333-279330) 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 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, we are currently focused on the development of nimacimab, either as monotherapy or 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. In addition, some of our assumptions about why nimacimab is worthy of future development and potential approval are based on data collected by other companies. Nimacimab may not have favorable results in its Phase 2a clinical trial in obesity.***

Clinical drug development is expensive and can take several 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 and early clinical trials, and many product candidates fail in clinical trials despite very promising early results. While the rationale to advance the development of nimacimab as a treatment for obesity is based in part on the efficacy of rimonabant, a non-peripherally restricted small molecule CB1 inhibitor that promoted weight loss in Phase 3 clinical trials, we may not observe similar efficacy in our Phase 2a clinical trial of nimacimab. Moreover, these and any future preclinical and clinical data may be susceptible to varying interpretations and analyses.

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 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.

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 independent institutional review boards (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 contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- 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, good clinical practices, or 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 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, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. 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. We may not be able to initiate or continue clinical trials if we are unable to locate a sufficient number of eligible subjects to participate in the clinical trials required by the FDA or comparable foreign regulatory authorities.

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 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, which would result in the delay of completion of such trials beyond our expected timelines.

***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 1 study of nimacimab, reported treatment emergent adverse events were diarrhea, headache, dizziness, upper respiratory tract infection, nausea and vomiting. However, further analysis may reveal adverse events inconsistent with the safety results 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 our product candidate, 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 our 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. The FDA or comparable foreign regulatory authorities, as the case may be, may 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:

- 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; or
- such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission.

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.

***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.

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.

Further, 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 candidates 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 our nimacimab expose 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 applicable foreign authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the 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 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.

***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 combination products, 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.

**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 contract research organizations, or 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, including our Phase 2a extension study 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 candidates, 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. 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 on Form 10-K. 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 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 biolgoical 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 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. 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 and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign 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**

***If we are not able to attract and retain highly qualified personnel, we may not be able to successfully implement our business strategy.***

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our 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. 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. 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 19, 2025, we had 16 full-time employees. 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 and amended by the California Privacy Rights Act, effective January 1, 2023, which imposes obligations on covered businesses to provide specific disclosures related to a business's collecting, using, and disclosing personal data and to respond to certain requests from California residents related to their personal data. 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. It also created 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 in Colorado, Connecticut, Delaware, Indiana, Iowa, Montana, Oregon, Tennessee, Texas, Utah, and Virginia and 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. Such laws could have different requirements that would make compliance challenging. In the event that we are subject to HIPAA, the CCPA, the CPRA or other 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, or EEA, the General Data Protection Regulation, or 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 revenues 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, or CJEU, invalidated the EU-US Privacy Shield Framework, or 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, or SCCs. In March 2022, the US and EU announced a new regulatory regime intended to replace the invalidated regulations with the Trans-Atlantic Data Privacy Framework, or 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; 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. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA.

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 on January 1, 2024, which eliminated the statutory Medicaid drug rebate cap, that was previously set at 100% of a drug's average manufacturer price, or AMP.

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 (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 (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. On June 30, 2023 the Centers for Medicare and Medicaid Services, or 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 that will be subject to 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 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.

***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. 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, see Note 11 to the Notes to the consolidated financial statements of the Company included in Part IV, Item 15 of this Annual Report on Form 10-K.

***The increasing use of social media 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. 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.

**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 on Form 10-K, 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. 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, 2024, the price per share of our common stock has ranged as low as $2.25 and as high as $19.41.

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. Such litigation, if instituted against us, 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 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. Such a delisting would likely have a negative effect on the price of our Common Stock and would impair your ability to sell or purchase our Common Stock when you wish to do so. 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 71% of our outstanding common stock as of December 31, 2024. 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 on Form 10-K, 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 1,301,573 have been exercised and 8,677,166 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, 2024, we have reserved; 3,036,603 shares for issuance upon the exercise of outstanding options, 503,113 shares for issuance upon the vesting of outstanding restricted stock units, 119,046 shares for issuance under our omnibus equity incentive plan, 286,500 shares for issuance under our inducement incentive plan, 192,016 shares for issuance under our 2022 employee stock purchase plan, and 11,880,110 shares for issuance upon the exercise of outstanding warrants. As of December 31, 2024, we had no outstanding preferred stock. As of December 31, 2024, we had 53,008,053 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, 2024, we had outstanding (i) warrants to purchase up to 11,880,110 shares of our common stock at exercise prices ranging from $0.001 to $1,250 per share, (ii) options to purchase up to 3,036,603 shares of our common stock at exercise prices ranging from $1.69 to $76.25 per share, (iii) 503,113 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, 2025, 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, 2024. 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 conflict, including the ongoing conflict between Russia and Ukraine, the Israel-Hamas war, impact of a 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 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. Further, the closures of Silicon Valley Bank, or SVB, Signature Bank and First Republic Bank and their placement into receivership with the Federal Deposit Insurance Corporation, or FDIC, created bank-specific and broader financial institution liquidity risk and concerns and future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages, impair the ability of companies to access near-term working capital needs, and create additional market and economic uncertainty. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur.

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. For example, as a result of the military conflict between Russia and Ukraine, the United States and its European allies announced the imposition of sanctions on certain industry sectors and parties in Russia and the regions of Donetsk and Luhansk in Ukraine, as well as enhanced export controls on certain products and industries. 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. The new political administration in the United States has signaled an intention to use tariffs more robustly in pursuing government policy and has already implemented some new tariffs. 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. We currently have limited research coverage by securities and industry analysts. 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 could be subject to securities class action litigation.***

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it 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, 2024, 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 11 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 19, 2025, the last reported sale price of our common stock on the Nasdaq Global Select Market was [$2.00] per share.

**Stockholders.** As of March 19, 2025, there were [190] 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, 2024, 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, 2024 and 2023 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), Bird Rock Bio Sub, Inc. ("BRB"), a Delaware corporation and Ruiyi Acquisition Corp, 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 August of 2024, we commenced our Phase 2a clinical trial, CBeyond™, for nimacimab. The CBeyond™ clinical trial includes 136 patients, 16 clinical trial sites and an exploratory combination arm with a GLP-1 receptor agonist to assess differences in weight loss, body composition, and other attributes. The CBeyond™ clinical trial is 100% enrolled and we expect to provide topline data near the end of the third quarter or the beginning of the four quarter 2025.

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.

On September 6, 2023, we filed a Certificate of Change and Certificate of Correction with the Secretary of State of the State of Nevada, which effected a reverse stock split, at a ratio of one-for-250, of the Company's issued and outstanding shares of common stock (the "Reverse Split"). The Reverse Split was effective on September 8, 2023. As a result of the Reverse Split, each two-hundred fifty (250) shares of common stock was combined into one (1) share of common stock and the total number of shares of common stock authorized was reduced from 5,000,000,000 to 20,000,000 and the number of shares of common stock issued and outstanding was reduced from 3,078,137,871 shares of common stock to 12,312,551 shares of common stock. Subsequently, on November 6, 2023, we increased our authorized shares of common stock to 100,000,000.

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) will allow 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 or manufacturing activities necessary to supply a Phase 3 clinical study.

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 have been 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. We also maintain office space in San Francisco, 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, 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. During the year ended December 31, 2023, we incurred $5,819,461 in research and development expense primarily related to our efforts in conducting the Phase 1 SBI-100 clinical trial and the manufacturing of the API required for the Phase 1 and Phase 2a SBI-100 OE clinical studies.

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.

*Cost to Acquire In-Process Research and Development ("IPR&D") Asset*

During the year ended December 31, 2023, we incurred a one-time non-cash charge of $21,215,214 related to the acquisition of our lead clinical asset, nimacimab. This in-process R&D was expensed when purchased in exchange for shares of our common stock, as its only future use was determined to be for drug development.

*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 and 2023, 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*

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. As of December 31, 2024, we were successful in our appeal of the judgement in the Ninth Circuit and the case was remanded back to the District Court for a new trial, as a result of which we adjusted 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. See Note 11 to the accompanying consolidated financial statements for more information.

*Other Expense*

Other expense primarily includes a gain from the sale of the Avalite Sciences, Inc. ("AVI") building (the "AVI building") (see Note 3 to the accompanying consolidated financial statements), and interest expense. In 2023, we also reported wind-down costs from our 2022 acquisition of EHT which we did not incur in 2024. These expenses are offset by interest income earned on our cash balances.

**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. While we expect certain recently adopted accounting pronouncements to impact our estimates in future periods, the impact upon adoption was not significant to our current estimates and operations.

**Results of Operations**

***Comparison of the years ended December 31, 2024 and 2023***

*Research and Development Expenses*

Below is a summary of our research and development expenses during the years ended December 31, 2024 and 2023:

| | Year Ended December 31, | | | |
|---|---|---|---|---|
| | 2024 | 2023 | $ Change 2024 vs. 2023 | % Change 2024 vs. 2023 |
| Research and development expenses | $18,701,694 | $ 5,819,461 | $ 12,882,233 | 221 % |

Research and development expenses for the year ended December 31, 2024 increased by $12,882,233 when compared to the year ended December 31, 2023. The increase in research and development expenses was primarily due to the following increases:

- Clinical study costs increased by $7,721,375 due to the planning and launch of the CBeyond™ study in August of 2024, which achieved 50% enrollment by the end of 2024. During 2024, we also completed our Phase 2a SBI-100 trial for glaucoma.
- Contract manufacturing costs increased by $1,234,445 due to nimacimab process intensification and drug resupply manufacturing runs which will allow us to seamlessly transition to a Phase 2b and build a scalable manufacturing process for future studies.
- Consulting costs increased by $691,185 to support our nimacimab program.
- Discovery research and development costs increased by $348,313 from non-clinical studies related to the development of a diet induced obesity model to demonstrate proof of concept and mechanism of action studies related to nimacimab.
- Salaries and stock-based compensation increased by $2,184,420 due to increased headcount to support our metabolic pipeline and organizational expertise.

- General business expenses increased by $459,054 due to increased travel and the write off of non-refundable deposits related to our glaucoma program.
- In addition, we recognized additional depreciation of $156,628 on specialized manufacturing equipment that was purchased in 2024 to support manufacturing activities.

*Cost to acquire IPR&D asset*

Below is a summary of our cost to acquire the IPR&D asset during the December 31, 2024 and 2023:

| | Year Ended December 31, | | | |
|---|---|---|---|---|
| | 2024 | 2023 | $ Change 2024 vs. 2023 | % Change 2024 vs. 2023 |
| Cost to acquire IPR&D asset | $ — | $21,215,214 | $(21,215,214) | (100)% |

Cost to acquire the IPR&D asset for the December 31, 2024, decreased by $21,215,214 as compared to the year ended December 31, 2023. The decrease is due to the cost to acquire nimacimab in the BRB Acquisition, which occurred in 2023.

*General and Administrative Expenses*

Below is a summary of general and administrative expenses during the years ended December 31, 2024 and 2023:

| | Year Ended December 31, | | | |
|---|---|---|---|---|
| | 2024 | 2023 | $ Change 2024 vs. 2023 | % Change 2024 vs. 2023 |
| General and administrative expenses | $17,725,741 | $ 7,852,340 | $ 9,873,401 | 126 % |

General and administrative expenses for the year ended December 31, 2024 increased by $9,873,401 as compared to the year ended December 31, 2023. The increase in general and administrative expenses was primarily due to the following:

- Salaries and stock-based compensation increased by $6,980,398 due to increased headcount and the recognition of stock based compensation expense 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. We also had an increase of $148,497 in human resources related fees to attract new talent.
- Legal, professional fees and consulting advisory increased by $1,397,512 due to one time services provided under a financial advisory agreement, professional services related to the registration of the resale of shares issued in the BRB Acquisition and the August 2023 PIPE Financing, the January and March 2024 PIPE Financings and general corporate legal fees associated with our uplisting to Nasdaq, the filing of our shelf registration statement, legal fees related to nimacimab patent prosecution, increased tax fees due to increased tax complexity and the entry into the ATM Agreement.
- General business expenses increased by $912,725 primarily due to increased insurance costs and regulatory fees associated with our uplisting to Nasdaq and the filing of our registration statements in connection with the January and March PIPE Financings. Other increases related to investments in building internal infrastructure and hosting internal and external corporate events.
- Travel and entertainment along with investor relations, marketing and public relations increased by $350,401, from increased activity to drive awareness for nimacimab.

*Change in Estimate for Legal Contingency*

Below is a summary of the estimated legal contingency during the years ended December 31, 2024 and 2023:

| | Year Ended December 31, | | | |
|---|---|---|---|---|
| | 2024 | 2023 | $ Change 2024 vs. 2023 | % Change 2024 vs. 2023 |
| Change in estimate for legal contingency | $(4,234,717) | $ (151,842) | $ (4,082,875) | 2689 % |

The change in estimate for legal contingency decreased by $4,082,875 for the year ended December 31, 2024, as compared to the year ended December 31, 2023. The adjustment of $4,234,717 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 11 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, 2024 and 2023:

| | Year Ended December 31, | | | |
|---|---|---|---|---|
| | 2024 | 2023 | $ Change 2024 vs. 2023 | % Change 2024 vs. 2023 |
| Income from insurance recovery | $(2,000,000) | $ — | $ (2,000,000) | 100 % |

The change in the income from insurance recovery increased by $2,000,000 for the year ended December 31, 2024 as compared to the year ended December 31, 2023. The increase 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, 2024 and 2023:

| | Year Ended December 31, | | | |
|---|---|---|---|---|
| | 2024 | 2023 | $ Change 2024 vs. 2023 | % Change 2024 vs. 2023 |
| Interest expense | 749,308 | 906,270 | (156,962) | (17) % |
| Interest income | (3,028,762) | (99,974) | (2,928,788) | 2930 % |
| Wind-down costs | — | 409,347 | (409,347) | (100) % |
| (Gain) loss from asset sale | (1,358,412) | 307,086 | (1,665,498) | (542) % |
| Debt conversion inducement expense | — | 1,383,285 | (1,383,285) | (100) % |
| Other expense (income) | 2,200 | (3) | 2,203 | (73433) % |
| **Total other expense (income), net** | **$(3,635,666)** | **$ 2,906,011** | **$ (6,541,677)** | **(225)%** |

For the year ended December 31, 2024, we had net other income of $3,635,666, which was primarily related to interest income of $3,028,762 and a gain from the divestiture of the AVI real estate and collections from Verdelite Sciences, Inc. ("VDL") related to its sale in 2023. Income was offset by interest expense of $749,308 (including cash and non-cash interest).

For the year ended December 31, 2023, we had net other expense of $2,906,011 primarily related to interest expense of $906,270 (including cash and non-cash interest), a non-cash charge of $1,383,285 related to the induced conversion of our multi-draw credit agreement with Emerald Health Sciences, Inc. (“Sciences”), dated October 5, 2018, as amended between April 29, 2020 and March 29, 2021 (the "Amended Credit Facility"), $409,347 in wind down costs associated with the EHT Acquisition (as defined below) and a $307,086 loss from the divestiture of VDL. The increase was offset by interest income of 99,974.

**Liquidity and Capital Resources**

We have incurred operating losses and negative cash flows from operations since inception and as of December 31, 2024, had working capital of $66,488,360 and an accumulated deficit of $130,949,672. As of December 31, 2024, the Company had cash and cash equivalents in the amount of $68,415,741. For the years ended December 31, 2024 and 2023, the Company incurred losses from operations of $30,192,718 and $34,735,173, respectively. For the years ended December 31, 2024 and 2023, the Company incurred net losses of $26,567,123 and $37,644,784, respectively. The Company expects to continue to incur significant losses and negative cash flows from operations through 2025 and expects to incur significant losses and negative cash flows from operations in the future.

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. The net proceeds raised from the January and March PIPE Financings, along with the reallocation of funds from the elimination of our ocular program, will allow us to fund our clinical trial for obesity through top-line Phase 2a data, complete process intensification manufacturing activities along with drug substance and product manufacturing work needed for future studies, plan for our Phase 2b dose ranging study and provide us with the ability to expand upon our metabolic program with our other research and development efforts.

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.

In July 2024, 1,301,573 pre-funded warrants, with an intrinsic value of $10,424,294, were exercised on a cashless basis, resulting in the issuance 1,301,410 shares of our common stock (see Note 7 to the accompanying consolidated financial statements).

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.

The Company's consolidated financial statements have been prepared on the basis of the Company continuing as a going concern for the next 12 months. Based on its current operational requirements, the Company believes that its current cash will be sufficient to fund its projected operations for at least 12 months from the date of the issuance of these consolidated financial statements. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect. Additionally, the process of testing product candidates in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain.

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, | |
|---|---|---|
| | **2024** | **2023** |
| Net cash and cash equivalents and restricted cash provided by (used in): | | |
| Operating activities | $ (25,237,480) | $ (13,952,178) |
| Investing activities | (245,615) | 6,596,456 |
| Financing activities | 83,562,181 | 16,443,270 |
| Net increase in cash and cash equivalents and restricted cash | $ 58,079,086 | $ 9,087,548 |

*Cash Flows from Operating Activities*

The primary use of cash and cash equivalents for our operating activities during the years ended December 31, 2024 and 2023 was to fund research and development activities for our clinical product candidates, nimacimab and 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, such as, stock-based compensation expense, non-cash interest expense related to the amortization of debt discounts on our convertible debt, a charge to induce the conversion of the Amended Credit Agreement in February 2023 and the expense related to the acquisition of our lead asset for obesity, nimacimab.

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 used in operating activities of $13,952,178 during the year ended December 31, 2023, reflected a net loss of $37,644,784, adjusted by aggregate non-cash charges of $24,161,913 and included a $469,307 decrease in our operating assets and liabilities. Non-cash charges included $124,251 of depreciation and amortization, $987,510 for stock-based compensation expense, $329,890 in non-cash interest expense from the amortization of the debt discount on our convertible debt, a gain of $151,842 from the courts decision to reduce the legal fees due to the plaintiff in the Cunning Lawsuit, $307,086 for a non-cash loss on the divestiture of VDL, a debt conversion inducement charge of $1,383,285 related to the conversion of the multi-draw credit agreement and in-process research and development expenses of $21,215,214 related to the acquisition of our lead asset, nimacimab. The net change in our operating assets and liabilities included a $306,442 increase in our prepaid expense and other current assets, a decrease in accounts payable of $701,285, and a $74,464 decrease in our accrued expense and other current liabilities.

*Cash Flows from Investing Activities*

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 AVI of $1,358,412. Cash provided from investing activities of $6,596,456 during the year ended December 31, 2023 consisted of our capital expenditures in relation to the purchase of property and equipment of $12,550, cash divested net of proceeds received from the sale of VDL of $5,532,266 and cash proceeds received from the BRB Acquisition of $1,076,740.

*Cash Flows from Financing Activities*

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.

During the year ended December 31, 2023, cash provided by financing activities included $11,734,947 in net proceeds received from the Company’s issuance on August 18, 2023 of an aggregate of 2,989,981 shares of common stock and accompanying warrants to purchase up to 2,325,537 shares of common stock pursuant to a PIPE financing arrangement (the "August 2023 PIPE Financing"), $4,973,684 in net proceeds from the issuance of a convertible note, offset by $259,335 in repayments on our insurance premium financing.

**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-31

**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 and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2024, 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, 2024, 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, 2024 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## Item 9B. Other Information.

***2025 Annual Meeting of Stockholders***

We currently intend to hold our 2025 annual meeting of stockholders (the "2025 Annual Meeting") on June 6, 2025.

Our Amended and Restated Bylaws ("Bylaws") provide notice procedures for stockholders to nominate a person as a director and to propose business to be considered by stockholders at an annual meeting of stockholders. A stockholder's notice must be delivered in writing to the Secretary of the Company at Skye Bioscience, Inc., 11250 El Camino Real, Suite 100, San Diego, CA 92130 and must set forth, as to each matter the stockholder proposes to bring before the annual meeting, the information required by our Bylaws. In order to be timely, a stockholder's notice must be delivered to the Secretary of the Company not later than the close of business on the 90th day nor earlier than the opening of business on the 120th day prior to the first anniversary of the date for the preceding year's annual meeting of stockholders; provided that in the event that the date of the annual meeting is more than 30 days before or more than 70 days after such anniversary date, notice by the stockholder to be timely must be so delivered not earlier than the close of business on the 120th day prior to the date of such annual meeting and not later than the close of business on the later of the 90th day prior to the date of such annual meeting or the 10th day following the day on which public announcement (as defined in the Bylaws) of the date of such annual meeting is first made by the Company.

Because we did not hold an annual meeting of stockholders in the year ended December 31, 2024 ("2024 Annual Meeting"), in order to be timely, a stockholder's notice must be delivered, as set forth above, not earlier than the close of business on February 6, 2025 and not later than the close of business on March 30, 2025. Stockholders who intend to solicit proxies in support of director nominees, other than the Company's nominees, must also provide notice that sets forth the information required by Rule 14a-19 under the Exchange Act.

In addition, because we did not hold a 2024 Annual Meeting, stockholder proposals submitted pursuant to Rule 14a-8 under the Exchange Act and intended to be presented at the 2025 Annual Meeting must be delivered, as set forth above, a reasonable time before the Company begins to print and send its proxy materials for the 2025 Annual Meeting in order to be considered for inclusion in the Company's proxy materials for that meeting. For purposes of the foregoing, we have determined that March 30, 2025 is a reasonable time before the Company intends to begin printing and sending its proxy materials for the 2025 Annual Meeting.

***Director and Officer Trading Arrangements***

On December 17, 2024, each of 5AM Partners VII, LLC (the general partner of 5AM Ventures VII, L.P.) and 5AM Partners II, LLC (the general partner of 5AM Ventures II, L.P. and 5AM Co-Investors II, L.P.) entered into a Stock Sale Plan (the "10b5-1 Plan") with Piper Sandler & Co. ("Piper Sandler"), pursuant to which Piper Sandler is authorized to sell up to an aggregate of 2,000,000 shares of Common Stock on behalf of 5AM Partners VII, LLC and 5AM Partners II, LLC during the period beginning on the later of (i) March 17, 2025 and (ii) two business days after filing the Issuer's Form 10-K for the year ending December 31 (but no later than April 16, 2025), and ending December 17, 2025, subject to earlier termination in accordance with the terms of the 10b5-1 Plan and applicable laws, rules and regulations. Transactions under the 10b5-1 Plan will be subject to certain price restrictions and other restrictions under the terms of the 10b5-1 Plan. The 10b5-1 Plan is intended to comply with the requirements of Rule 10b5-1(c) promulgated under the Act. Andrew Schwab, a member of the Board of Directors of the Company, is a managing member of each of 5AM Partners VII, LLC and 5AM Partners II, LLC and may be deemed to share voting and investment power over the shares held by 5AM Partners VII, LLC and 5AM Partners II, LLC. 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 2025 Annual Meeting (the "Proxy Statement"), which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2024, 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.

### 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 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**

## 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 sheets of Skye Bioscience, Inc. and Subsidiaries (the "Company") as of December 31, 2024 and 2023, the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, based on our audits, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

### Basis for Opinion

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

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

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

### Critical Audit 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/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2022.

**Morristown, NJ**
**March 20, 2025**

**SKYE BIOSCIENCE, INC. AND SUBSIDIARIES**
**CONSOLIDATED BALANCE SHEETS**

| | December 31 | |
|---|---|---|
| **ASSETS** | **2024** | **2023** |
| **Current assets** | | |
| Cash and cash equivalents | $ 68,415,741 | $ 1,256,453 |
| Restricted cash | — | 9,080,202 |
| Prepaid expenses | 201,962 | 194,259 |
| Other current assets | 2,209,544 | 1,119,929 |
| Total current assets | 70,827,247 | 11,650,843 |
| | | |
| Property and equipment, net | 1,432,752 | 43,276 |
| Operating lease right-of-use asset | 449,864 | 237,983 |
| Other assets | 53,910 | 8,309 |
| Total assets | $ 72,763,773 | $ 11,940,411 |
| | | |
| **LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)** | | |
| **Current liabilities** | | |
| Accounts payable | $ 569,252 | $ 956,754 |
| Accrued interest - related party | — | 126,027 |
| Accrued interest - legal contingency | — | 234,750 |
| Accrued payroll liabilities | 1,114,255 | 888,381 |
| Other current liabilities | 654,201 | 991,805 |
| Estimate for accrued legal contingencies and related expenses | 1,818,751 | 6,259,246 |
| Convertible note - related party, net of discount | — | 4,371,998 |
| Operating lease liability, current portion | 182,428 | 72,038 |
| Total current liabilities | 4,338,887 | 13,900,999 |
| | | |
| **Non-current liabilities** | | |
| Operating lease liability, net of current portion | 273,162 | 171,230 |
| Total liabilities | 4,612,049 | 14,072,229 |
| | | |
| **Commitments and contingencies (Note 11)** | | |
| | | |
| **Stockholders' equity (deficit)** | | |
| Preferred stock, $0.001 par value; 200,000 shares authorized at December 31, 2024 and 2023; no shares issued and outstanding at December 31, 2024 and 2023 | — | — |
| Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2024 and 2023, respectively; 30,974,559 and 12,349,243 shares issued and outstanding at December 31, 2024 and 2023, respectively | 30,975 | 12,349 |
| Additional paid-in-capital | 199,070,421 | 102,238,382 |
| Accumulated deficit | (130,949,672) | (104,382,549) |
| Total stockholders' equity (deficit) | 68,151,724 | (2,131,818) |
| Total liabilities and stockholders' equity (deficit) | $ 72,763,773 | $ 11,940,411 |

See accompanying notes to the consolidated financial statements.

**SKYE BIOSCIENCE, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF OPERATIONS**

| | Year Ended December 31 | |
|---|---|---|
| | **2024** | **2023** |
| **Operating expenses** | | |
| Research and development | $ 18,701,694 | $ 5,819,461 |
| Cost to acquire IPR&D asset | — | 21,215,214 |
| General and administrative | 17,725,741 | 7,852,340 |
| Change in estimate for legal contingency | (4,234,717) | (151,842) |
| Income from insurance recovery | (2,000,000) | — |
| Total operating expenses | 30,192,718 | 34,735,173 |
| **Operating loss** | (30,192,718) | (34,735,173) |
| **Other (income) expense** | | |
| Interest expense | 749,308 | 906,270 |
| Interest income | (3,028,762) | (99,974) |
| Wind-down costs | — | 409,347 |
| (Gain) loss from asset sale | (1,358,412) | 307,086 |
| Debt conversion inducement expense | — | 1,383,285 |
| Other expense (income) | 2,200 | (3) |
| Total other (income) expense, net | (3,635,666) | 2,906,011 |
| **Loss before income taxes** | (26,557,052) | (37,641,184) |
| Provision for income taxes | 10,071 | 3,600 |
| **Net loss** | $ (26,567,123) | $ (37,644,784) |
| **Loss per common share** | | |
| Basic | $ (0.73) | $ (5.37) |
| Diluted | $ (0.73) | $ (5.37) |
| **Weighted average shares of common stock outstanding used to compute loss per share:** | | |
| Basic | 36,486,519 | 7,006,038 |
| Diluted | 36,486,519 | 7,006,038 |

See accompanying notes to the consolidated financial statements.

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

| | Year Ended December 31 | |
|---|---|---|
| | **2024** | **2023** |
| **Cash flows from operating activities:** | | |
| Net loss | $ (26,567,123) | $ (37,644,784) |
| | | |
| Adjustments to reconcile net loss to net cash, cash equivalents and restricted cash used in operating activities: | | |
| Write-down of vendor deposits | 325,610 | — |
| Depreciation and amortization | 298,640 | 124,251 |
| Net loss (gain) on disposal of asset | 10,794 | (4,080) |
| Stock-based compensation expense | 8,317,480 | 987,510 |
| Change in fair value of derivative liability | — | (3) |
| Amortization of debt discount | 599,006 | 329,890 |
| Change in estimate for legal contingencies | (4,234,717) | (151,842) |
| (Gain) loss from divestiture of asset | (1,358,412) | 307,086 |
| Debt conversion inducement expense | — | 1,383,285 |
| Accrued interest conversion expense | — | 15,952 |
| Cost to acquire IPR&D asset | — | 21,215,214 |
| Foreign currency remeasurement gain | — | (45,350) |
| Changes in assets and liabilities: | | |
| Prepaid expenses | (7,703) | 795,232 |
| Other assets | (45,601) | — |
| Other current assets | (1,415,225) | (488,790) |
| Accounts payable | (586,533) | (576,384) |
| Accounts payable – related parties | — | (124,901) |
| Accrued interest – related party | (126,027) | 126,027 |
| Accrued interest - legal contingency | (234,750) | 234,750 |
| Accrued payroll liabilities | 225,874 | 230,647 |
| Other current liabilities | (344,351) | (493,472) |
| Other current liabilities - related parties | — | (95,850) |
| Operating lease liability | (94,442) | (76,566) |
| Net cash, cash equivalents and restricted cash used in operating activities | (25,237,480) | (13,952,178) |
| | | |
| Cash flows from investing activities: | | |
| Proceeds from asset sales, net of legal expenses | 1,358,412 | 5,532,266 |
| Purchases of property and equipment | (1,604,027) | (12,550) |
| Cash acquired in asset acquisition | — | 1,076,740 |
| Net cash cash equivalents and restricted cash (used in) provided by investing activities | (245,615) | 6,596,456 |
| | | |
| Cash flows from financing activities: | | |
| Proceeds from PIPE financing, net of $6,434,447 and $265,053 issuance costs, respectively | 83,556,563 | 11,734,947 |
| Proceeds from convertible note - related party | — | 4,973,684 |
| Financing costs allocated to warrants issued with convertible debt | — | (6,026) |
| Proceeds from options exercises | 5,618 | — |
| Repayment of loan payable | — | (259,335) |
| Net cash, and cash equivalents and restricted cash provided by financing activities | 83,562,181 | 16,443,270 |
| | | |
| **Net increase in cash and cash equivalent and restricted cash** | 58,079,086 | 9,087,548 |
| | | |
| **Cash, cash equivalents and restricted cash, beginning of year** | $ 10,336,655 | $ 1,249,107 |
| | | |
| **Cash, cash equivalents and restricted cash, end of year** | $ 68,415,741 | $ 10,336,655 |
| | | |
| *Supplemental disclosures of cash-flow information:* | | |
| Reconciliation of cash and cash equivalent and restricted cash: | | |

| | | |
|---|---|---|
| Cash and cash equivalent | $ 68,415,741 | $ 1,256,453 |
| Restricted cash | — | 9,080,202 |
| Total cash and cash equivalent and restricted cash shown in the consolidated statements of cash flows | $ 68,415,741 | $ 10,336,655 |
| | | |
| Cash paid during the year for: | | |
| Interest | $ 433,336 | $ 198,352 |
| Income taxes | 5,200 | 3,600 |
| | | |
| *Supplemental disclosures of non-cash financing activities:* | | |
| Financing of insurance premium | $ — | $ 203,884 |
| Common stock warrant exercises | — | 282,906 |
| Conversion of multi-draw credit agreement | — | 1,565,470 |
| Conversion of accrued interest due to related party | — | 31,766 |
| Right of use asset obtained in exchange for operating lease liabilities | 306,764 | 241,134 |
| Stock issued for assets | — | 20,532,846 |
| 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 | Stockholders' (Deficit) Equity |
| | Shares | Amounts | | | |
| **Balance, December 31, 2022** | **3,654,119** | **$ 3,654** | **$ 63,726,057** | **$ (66,737,765)** | **$ (3,008,054)** |
| Stock-based compensation expense | 10,333 | 10 | 987,500 | — | 987,510 |
| Exercise of common stock warrants | 66,566 | 67 | 282,839 | — | 282,906 |
| Conversion of multi-draw credit agreement - related party and accrued interest | 165,517 | 166 | 2,980,355 | — | 2,980,521 |
| Common stock issued in acquisition of IPR&D asset | 5,436,378 | 5,436 | 21,604,150 | — | 21,609,586 |
| PIPE Financing, net of equity issuance costs $265,053 | 2,989,981 | 2,990 | 11,731,957 | — | 11,734,947 |
| Warrants issued with convertible note | — | — | 925,550 | — | 925,550 |
| Common stock issued for fractional share adjustment in reverse stock split | 26,349 | 26 | (26) | — | — |
| Net loss for the year ended December 31, 2023 | — | — | — | (37,644,784) | (37,644,784) |
| **Balance, December 31, 2023** | **12,349,243** | **$ 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** |

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 biopharmaceutical company developing next-generation molecules that modulate G protein-coupled receptors to treat obesity, overweight and metabolic diseases.

On August 18, 2023, the Company 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 (the "BRB Merger Agreement"), 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”). In connection with the BRB Acquisition, Bird Rock Bio, Inc. changed its name from Bird Rock Bio, Inc. to Bird Rock Bio Sub, Inc. ("BRB"). In the BRB Acquisition, the Company issued to certain former stockholders of BRB an aggregate of 5,436,378 shares of the common stock of the Company, valued at $21,609,586 (See Note 3 to the accompanying consolidated financial statements).

As of December 31, 2024, 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.

*Impact of Geopolitical and Macroeconomic Factors*

It is possible that the Company may encounter supply chain issues related to global economic and political conditions such as a lack of production or laboratory resources, pandemics or cyberattacks that could cause business disruptions and clinical trial delays which will need to be managed in the future. There may also be significant uncertainty resulting from the impact of other geopolitical and macroeconomic factors, including global pandemics, inflation, supply chain issues, rising interest rates, future bank failures, increased geopolitical tensions between the U.S. and China and the impact of the Russia/Ukraine conflict and the Israel-Hamas war.

## 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, primarily the separate classification of prepaid expenses and other current assets on the Company's consolidated balance sheet, and consolidated statement of cash flows, the classification of legal costs and accruals as part of the estimate for accrual for legal contingencies and related expenses on the Company's consolidated balance sheet, and consolidated statement of cash flows and change in fair value of derivative liability and interest expense on the consolidated statement of operations. Such reclassifications did not have a material impact on the consolidated financial statements.

*Assets Held for Sale*

On November 10, 2022, the Company completed the acquisition of Emerald Health Therapeutics ("EHT") (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 Verdélite Sciences, Inc. ("VDL"). As a result, EHTC and VDL were considered held for sale since the EHT Acquisition and the Company has classified the associated assets of VDL as held for sale on the Consolidated Balance Sheets and the period costs related to both EHTC and VDL have been presented as wind-down costs in the Consolidated Statements of Operations. EHTC was divested on December 28, 2022, and VDL was divested on February 9, 2023 (see Note 3 to the accompanying consolidated financial statements). Assets meeting the held-for-sale criteria are classified as held for sale on the Consolidated Balance Sheets in subsequent periods until sold.

Assets that meet the held-for-sale criteria are held for sale and reported at the lower of their carrying value or their fair value, less estimated costs to sell. Changes in fair value are recorded as a gain or loss in the results of operations but not to exceed the original carrying value. Due to the asset acquisition accounting on the date of the EHT Acquisition, Avalite Sciences, Inc. ("AVI") had no initial carrying value. Refer to Note 3 of the accompanying consolidated financial statements for further information.

*Derecognition of Nonfinancial Assets*

The Company generally accounts for sales of nonfinancial assets that are outside the scope of our ordinary activities under ASC 610-20, Other Income - Gains and Losses from the Derecognition of Nonfinancial Assets. Pursuant to ASC 610-20, the Company applies the guidance in ASC 606 to determine if a contract exists, identify the distinct nonfinancial assets, and determine when control transfers and, therefore, when to derecognize the nonfinancial asset. Additionally, the Company applies the measurement principles of ASC 606 to determine the amount of consideration, if any, to include in the calculation of the gain or loss for the sale of the nonfinancial asset. Refer to Note 3 for further information.

*Principles of Consolidation*

The accompanying consolidated financial statements as of December 31, 2024, include the accounts of the Company and its wholly owned subsidiaries SKYE Bioscience Australia, EHT, BRB, Ruiyi Acquisition Corporation, 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 Company's estimation of the 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, Cash Equivalents and Restricted Cash***

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.

As of December 31, 2024 there is no restricted cash on the balance sheet (refer to Note 11). As of December 31, 2023, restricted cash on the balance sheet collateralized an irrevocable letter of credit.

***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, 2024 and 2023. 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.

***Convertible Instruments***

The Company adopted ASU 2020-06. Since the adoption of ASU 2020-06, the Company recorded its convertible debt at face value less unamortized issuance costs. Issuance costs are amortized to Interest expense in its Consolidated Statements of Operations using the effective interest method over the expected term of the convertible debt. The Company assesses the short-term and long-term classification of its convertible debt on each balance sheet date. Whenever the holders have a contractual right to convert, the carrying amount of the convertible debt is reclassified to current liabilities.

***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.

***Debt Issuance Costs and Interest***

Discounts related to bifurcated derivatives, freestanding instruments issued in bundled transactions, and issuance costs are recorded as a reduction to the carrying value of the debt and amortized over the life of the debt using the effective interest method. The Company makes changes to the effective interest rate, as necessary, on a prospective basis.

***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.

Similarly, costs incurred to acquire in-process research and development ("IPR&D") are charged to research and development expense in the situation where the Company has not identified an alternative future use and are capitalized in the situation where there is an alternative future use. All costs associated with the acquisition of IPR&D have been expensed 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 subject to vesting, restricted stock units, warrants to purchase common stock and common shares underlying convertible debt instruments 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 9).

***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.

***Asset Acquisitions***

The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen is met, the transaction is accounted for as an asset acquisition. If the screen is not met, further determination is required as to whether or not the Company has acquired inputs and processes that have the ability to create outputs which would meet the definition of a business. Significant judgment is required in the application of the screen test to determine whether an acquisition is a business combination or an acquisition of assets.

For asset acquisitions, a cost accumulation model is used to determine the cost of an asset acquisition. Common stock, warrants and options issued as consideration in an asset acquisition are generally measured based on the acquisition date fair value of the equity interests issued. The Company refers to ASC 718 and utilizes a Black-Scholes Model to value the options and warrants issued is an asset acquisition and includes the fair value of such awards in the purchase consideration. Direct transaction costs are recognized as part of the cost of an asset acquisition. The Company also evaluates which elements of a transaction should be accounted for as a part of an asset acquisition and which should be accounted for separately. Consideration deposited into escrow accounts are evaluated to determine whether it should be included as part of the cost of an asset acquisition or accounted for as contingent consideration. Amounts held in escrow where we have legal title to such balances but where such accounts are not held in the Company's name, are recorded on a gross basis as an asset with a corresponding liability in our consolidated balance sheet. Unless an acquired asset is expensed at the date of acquisition, in accordance with other applicable GAAP, the cost of an asset acquisition, including transaction costs, are allocated to identifiable assets acquired and liabilities assumed based on a relative fair value basis. Goodwill is not recognized in an asset acquisition. Any difference between the cost of an asset acquisition and the fair value of the net assets acquired is allocated to the non-monetary identifiable assets based on their relative fair values. However, as of the date of acquisition, if certain assets are carried at fair value under other applicable GAAP the consideration is first allocated to those assets with the remainder allocated to the non-monetary identifiable assets based on a relative fair value basis.

***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 $493,362 for the year ended December 31, 2024 related to incentives earned in the prior year and $180,374 for the year ended December 31, 2023. As of December 31, 2024 and 2023, the Company has recognized $8,151 and $540,604, respectively, in other current assets in its Consolidated Balance Sheets.

***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”) or Australian dollar (“AUD”). Assets and liabilities are remeasured based on the exchange rates at the balance sheet date 0.6952 for the CAD, 0.623 for the AUD as of December 31, 2024 and 0.7549 for the CAD and 0.6818 for the AUD as of December 31, 2023, while expense accounts are remeasured at the weighted average exchange rate for the period 0.7023 for the CAD and 0.6342 for the AUD for the year ended December 31, 2024 and 0.7453 for the CAD and 0.6697 for the AUD as of December 31, 2023. 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, 2024 and 2023, the Company recorded foreign currency remeasurements of $148,023 and $61,767, 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, 2024 and 2023, the Company recorded foreign currency transaction loss of $49,986 and gain of $9,143, respectively, which is reflected in the general and administrative expenses 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 11 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 June 2016, the Financial Accounting Standards Board ("FASB") issued Account Standards Update ("ASU") No. 2016-13, *Financial Instruments—Credit Losses* (Topic 326): Measurement of Credit Losses on Financial Instruments, which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. This ASU replaces the existing incurred loss impairment model with an expected loss model. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. These changes will result in earlier recognition of credit losses. The amendments in this ASU are effective for the Company for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company adopted ASU 2016-13 as of January 1, 2023 and the adoption did not have a material impact on the Company's consolidated financial statements and related disclosures.

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. The new standard reduces the number of accounting models for convertible debt instruments, amends the accounting for certain contracts in an entity's own equity, and modifies how certain convertible instruments and contracts that may be settled in cash or shares impact the calculation of diluted earnings per share. Specifically, the guidance removes certain accounting models that separate the embedded conversion features from the host contract for convertible instruments and requires the use of the if-converted method to calculate diluted earnings per share. The adoption of this standard did not have an impact on the Company's consolidated financial statements.

In November 2023, the 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 12.

*Recent Accounting Pronouncements Not Yet Adopted*

In December 2023, the FASB issued 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 is currently evaluating the impact the adoption of this ASU will have on its consolidated financial statements and related disclosures.

In November 2024, the Financial Accounting Standards Board (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.

## 3. Asset Acquisitions and Dispositions

***BRB Acquisition***

On August 18, 2023, the Company acquired BRB pursuant to the BRB Merger Agreement. The purpose of the acquisition was to acquire BRB's clinical asset, nimacimab, an antibody targeting the CB1 receptor. Pursuant to the BRB Acquisition, the Company issued 3,872,184 shares of common stock to the former preferred shareholders of BRB equal to $20,000,000 in base merger consideration priced at $5.16.

In addition, the former preferred shareholders of BRB were entitled to additional merger consideration for each dollar invested in the August 2023 PIPE Financing (as defined in Note 7). Because the August 2023 PIPE Financing and the BRB Acquisition occurred contemporaneously and in contemplation of each other, in accounting for the transaction, the Company allocated the shares issued as additional merger consideration between the BRB Acquisition and PIPE Financing using a residual allocation method, whereby the fair value of the consideration transferred was first allocated to the monetary assets and August 2023 PIPE Financing proceeds with the remainder allocated to the IPR&D asset. As a result, 1,564,194 additional shares of common stock were allocated to the BRB Acquisition.

Below is a summary of the total consideration, assets acquired and the liabilities assumed in connection with the BRB Acquisition:

| | August 18, 2023 | |
|---|---|---|
| ***Purchase consideration*** | | |
| Common stock | $ 21,609,586 | (a) |
| **Total consideration** | **$ 21,609,586** | |
| ***Assets acquired and liabilities assumed:*** | | |
| IPR&D asset | $ 21,215,214 | |
| Cash and cash equivalents | 1,076,740 | |
| Prepaid expenses | 4,800 | |
| Accounts payable | (73,473) | |
| Other current liabilities | (613,695) | |
| **Total net assets acquired** | **$ 21,609,586** | |

(a) Equal to the aggregate common shares issued of 5,436,378, multiplied by the Company's closing stock price of $3.975 as of August 18, 2023.

The cost to acquire the IPR&D asset related to nimacimab was expensed on the date of the BRB Acquisition as it was determined to have no future alternative use. Accordingly, costs associated with the BRB Acquisition to acquire the asset were expensed as incurred.

**Acquisition of Emerald Health Therapeutics, Inc.**

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, is complete.

***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) Loss 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 November 10, 2022, EHT and C3 Centre Holding Inc., a third-party, entered into a share purchase agreement, executed as of November 8, 2022, as amended (the "Verdélite SPA") pursuant to which C3 would acquire all of the outstanding shares of VDL, the holder of EHT's most significant real estate asset.

On February 9, 2023, upon closing the transactions contemplated by the Verdélite SPA, the Company sold all of the outstanding shares of VDL for an aggregate purchase price of approximately $9,451,233. Prior to closing the EHT Acquisition, EHT received a $557,705 cash deposit, which was considered in the sale as of the closing date. Upon closing, the Company received gross proceeds, net of legal and advisory fees as of the closing date, of $5,532,266, with the remainder of the purchase price to be paid in accordance with an installment schedule as determined by the Verdélite SPA.

The Company recognized the sale of VDL when control transferred on February 9, 2023. In accordance with recognition guidance, the Company has determined to fully reserve for the remaining receivables and will record a gain on the sale when additional cash payments are received. For the year ended December 31, 2023, the Company has recorded a loss on sale of asset of $307,086 in other expense based on the difference between the carrying amount of the assets sold and the net cash proceeds.

On July 17, 2024, the Company entered into a transaction, release and discharge agreement with the purchaser of 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 received the first installment payment of $213,404 recorded as a (Gain) Loss from Asset Sales within the Other Income and Expense section of the Company's Consolidated Statement of Operations.

## 4. Property and Equipment, Prepaid Expenses, Other Current Assets and Liabilities

Property and equipment, net consists of the following:

| | As of December 31 | |
|---|---|---|
| | **2024** | **2023** |
| Machinery and equipment | $ 1,527,419 | $ 78,024 |
| Furniture and fixtures | 18,184 | — |
| Computer equipment | 96,744 | 46,732 |
| Leasehold improvements | 23,918 | 13,954 |
| Total property and equipment, gross | 1,666,265 | 138,710 |
| Less: accumulated depreciation and amortization | (233,513) | (95,434) |
| **Total property and equipment, net** | **$ 1,432,752** | **$ 43,276** |

Depreciation and amortization expense for the twelve months ended December 31, 2024 and twelve months ended December 31, 2023 was $203,757 and $49,909, respectively.

Prepaid expenses consist of the following:

| | As of December 31 | |
|---|---|---|
| | 2024 | 2023 |
| Prepaid clinical expenses | $ 13,078 | $ 61,352 |
| Total other prepaid expenses | 188,884 | 132,907 |
| | **$ 201,962** | **$ 194,259** |

Other current assets consist of the following:

| | As of December 31 | |
|---|---|---|
| | 2024 | 2023 |
| AusIndustry incentive | $ 8,151 | $ 540,604 |
| Vendor deposits | 1,997,274 | 403,439 |
| Other tax receivables | 5,065 | 158,242 |
| Other current assets | 199,054 | 17,644 |
| | **$ 2,209,544** | **$ 1,119,929** |

Other current liabilities consist of the following:

| | As of December 31 | |
|---|---|---|
| | 2024 | 2023 |
| Research and development costs | $ 325,415 | $ 467,784 |
| Legal expenses | 114,359 | 251,466 |
| EHT Acquisition related liability | — | 180,897 |
| Consulting and professional fees | 109,375 | 69,468 |
| Other accrued liabilities | 105,052 | 22,190 |
| | **$ 654,201** | **$ 991,805** |

**5. 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, 2024 are summarized as follows:

| Source | Exercise Price | Remaining Term (Years) | Number of Warrants Outstanding |
|---|---|---|---|
| 2015 Common Stock Warrants | 1,250.00 | 0.31 | 400 |
| 2016 Common Stock Warrants to Service Providers | 287.50 | 1.83 | 160 |
| 2020 Common Stock Warrants to Placement Agent | 20.00 | 0.58 | 32,668 |
| 2021 Inducement Warrants | 37.50 | 1.57 | 84,667 |
| 2021 Inducement Warrants to Placement Agent | 47.00 | 1.57 | 5,927 |
| 2021 Common Stock Warrants | 22.50 | 1.74 | 311,113 |
| 2021 Common Stock Warrants to Placement Agent | 27.50 | 1.74 | 21,778 |
| February 2020 EHT Common Stock Warrants* | 37.25 | 0.11 | 80,694 |
| August 2023 Convertible Note Common Stock Warrants | 5.16 | 8.63 | 340,000 |
| August 2023 PIPE Financing Common Stock Warrants | 5.16 | 8.63 | 2,325,537 |
| January 2024 Pre-Funded Warrants Common Stock | 0.001 | Indefinite | 8,677,166 |
| **Total warrants outstanding as of December 31, 2024** | | | **11,880,110** |

As of December 31, 2024, 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 7), the Company issued the Pre-Funded Warrants (as defined in Note 7). 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.

***August 2023 PIPE Financing Common Stock Warrants***

In connection with the August 2023 PIPE Financing (as defined in Note 7), the Company issued 2,325,537 common stock warrants. The warrants were equity classified at issuance and $4,784,894 of the gross proceeds from the August 2023 PIPE Financing were allocated to the common stock warrants on a relative fair value basis. The warrants vested immediately upon issuance and the fair value of $7,881,972 was determined using the Black-Scholes Merton option pricing model with the following assumptions:

| | August 18, 2023 |
|---|---|
| Dividend yield | 0.00 % |
| Volatility factor | 87.88 % |
| Risk-free interest rate | 4.26 % |
| Expected term (years) | 10.00 |
| Underlying common stock price | $ 5.16 |

***August 2023 Convertible Note Common Stock Warrants***

In connection with the Convertible Note (as defined in Note 6), the Company issued 340,000 common stock warrants. The warrants were equity classified at issuance and $931,576 of the gross proceeds from the Convertible Note were allocated to the common stock warrants on a relative fair value basis. The warrants vested immediately upon issuance and the fair value of $1,144,886 was determined using the Black-Scholes Merton option pricing model with the following assumptions:

| | August 18, 2023 |
|---|---|
| Dividend yield | 0.00 % |
| Volatility factor | 87.88 % |
| Risk-free interest rate | 4.26 % |
| Expected term (years) | 10 |
| Underlying common stock price | $ 5.16 |

***February 2023 Sciences Warrant Exercises***

Effective February 16, 2023, the Company and Sciences entered into a Master Transaction Agreement (the "MTA"). Under the MTA, Sciences agreed to exercise 66,566 common stock warrants at $4.25 per share (the "MTA Warrants"). Under the MTA, the parties agreed that the aggregate proceeds from the exercise of the MTA Warrants of $282,906 was to be paid through a reduction of the outstanding borrowings under the Amended Credit Agreement (as defined in Note 6). On February 22, 2023, the Company issued 66,566 shares of common stock to Sciences in connection with the exercise of the MTA Warrants (as defined in Note 7).

**6. Debt**

The Company’s convertible debt consists of the following:

| | As of December 31, 2023 |
|---|---|
| Total principal value of convertible note - related party, net of debt discount | $ 5,000,000 |
| Unamortized debt discount | (610,749) |
| Unamortized debt issuance costs | (17,253) |
| **Carrying value of total convertible debt—related party** | **$ 4,371,998** |

***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 Financing") (Note 5). 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. In addition, the Company recorded $6,026 in equity issuance costs as a deduction to additional paid in capital in the Statements of Stockholders' Deficit.

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%.

***Bridge Loan***

On July 24, 2023, the Company entered into a loan agreement in the principal amount of $250,000 (the "Bridge Loan") with MFDI, LLC. The Bridge Loan was obtained in order to provide bridge financing for the operations of the Company until it completed the BRB Acquisition. Concurrent with the closing of the BRB Acquisition, August 2023 PIPE Financing and Convertible Note Financing, the Bridge Loan was cancelled and converted into an investment in the August 2023 PIPE Financing (as defined in Note 7). All interest and rights related to the Bridge Loan were concurrently cancelled.

***Insurance Premium Loan Payable***

On February 28, 2023, the Company entered into an annual financing arrangement for a portion of its Directors and Officers Insurance Policy (the "D&O Insurance") with First Insurance Funding in an amount of $203,884. The loan was payable in equal monthly installments of $23,374, matured on January 31, 2024, and bore interest at a rate 4.24% per annum. As of December 31, 2023 a total of $21,238 remained in prepaid expenses and the loan has been repaid.

On February 28, 2022, the Company entered into an annual financing arrangement for a portion of its Directors and Officers Insurance Policy with First Insurance Funding in an amount of $275,537. The loan was payable in equal monthly installments of $31,150, matured on January 31, 2023 and bore interest at a rate 4.17% per annum.

***Interest Expense***

The Company's interest expense consists of the following:

| | Year Ended December 31, | |
|---|---|---|
| | **2024** | **2023** |
| Related party interest expense – stated rate | $ 302,740 | $ 202,254 |
| Insurance premium loan payable – stated rate | — | 6,485 |
| Legal judgment estimated interest (income) expense | (234,750) | 234,750 |
| Bond premium | 59,929 | 59,929 |
| Premium on irrevocable letter of credit | 22,383 | 69,861 |
| Other interest expense | — | 3,100 |
| Non-cash interest expense: | | |
| Amortization of debt discount | 582,550 | 320,828 |
| Amortization of transaction costs | 16,456 | 9,063 |
| | **$ 749,308** | **$ 906,270** |

**7. 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, | |
|---|---|---|
| | **2024** | **2023** |
| Options issued and outstanding | 3,036,603 | 498,298 |
| Awards available for grant under the Amended and Restated Omnibus Incentive Plan | 119,046 | 487,672 |
| Shares available for issuance under ESPP Plan | 192,016 | 112,000 |
| Shares for issuance under our Inducement Plan | 286,500 | — |
| Restricted stock units issued and outstanding | 503,113 | 847,777 |
| Unreleased restricted stock awards issued to a service provider | — | 5,000 |
| Common stock underlying the Convertible Note - Related Party | — | 968,973 |
| Warrants issued and outstanding | 11,880,110 | 3,280,940 |
| | **16,017,388** | **6,200,660** |

***Increase to Authorized Shares of Capital Stock***

On November 6, 2023, the Company increased its authorized shares of common stock to 100,000,000.

***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.

*August 2023 PIPE Financing*

Concurrently with the BRB Acquisition and the Convertible Note Financing, on August 15, 2023, the Company entered into the August 2023 PIPE Financing, pursuant to which on August 18, 2023, the Company issued an aggregate of 2,989,981 shares of common stock and accompanying warrants to purchase up to 2,325,537 shares of common stock (the "August 2023 PIPE Financing Common Stock Warrants*") (Note 5*) for an aggregate purchase price of $12,000,000. The August 2023 PIPE Financing was priced at $5.16 per share based on the 60-day volume-weighted average share price preceding August 15, 2023. The two lead investors in the August 2023 PIPE Financing were also former preferred shareholders of BRB. As an incentive to participate in the August 2023 PIPE Financing, the BRB Merger Agreement entitled each BRB stockholder participating in the August 2023 PIPE Financing an additional share of common stock for every share of common stock purchased in the August 2023 PIPE Financing. As a result, the two former BRB preferred shareholders who participated in the August 2023 PIPE Financing were issued an additional 2,228,638 shares of common stock. Because the August 2023 PIPE Financing and BRB Acquisition occurred contemporaneously and in contemplation of one another, the Company allocated 664,444 of the common shares issued in the BRB Acquisition to the August 2023 PIPE Financing (Note 3).

In connection with the August 2023 PIPE Financing, the Company incurred $265,053 in direct equity issuance costs for net proceeds of $11,734,947.

***Conversion of Debt***

On August 8, 2024, the Company issued 968,973 shares of common stock to MFDI upon conversion in full of the Convertible Note (see Note 6).

During the year ended December 31, 2023, the Company issued 165,517 shares of common stock to Sciences. The shares were issued in conjunction with the MTA, in exchange for the remaining principal balance plus accrued interest less the aggregate exercise price of $282,905 from the exercise of the MTA Warrants in the amount of $1,597,236 at a conversion price of $9.65 (Note 6).

***BRB Acquisition***

On August 18, 2023, the Company issued an aggregate of 5,436,378 shares of common stock in connection with the BRB Acquisition (Note 3).

***Stock Issued for Services***

For the twelve months ended December 31, 2024 and 2023, the Company released 5,000 and 5,000 shares, respectively, of common stock to a service provider (Note 8).

***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 1,301,573 shares of Company's common stock.

*Common Stock Warrant Exercises*

During the year ended December 31, 2023, 66,566 of the outstanding stock warrants held by Sciences in conjunction with the MTA, with an intrinsic value of $332,830 were exercised in exchange for 66,566 shares of common stock for proceeds of $282,906 which were applied to the balance of the Amended Credit Agreement (Note 6).

***Restricted Stock Units Released***

During 2024 a total of 634,664 RSUs were vested and settled.

On December 14, 2023, the Company settled 5,333 RSUs that had vested to executives of the Company (Note 8).

**8. 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, 2024, the shares available for future grant under the Amended and Restated Plan are as follows:

| | Shares Available for Grant |
|---|---|
| **Available as of December 31, 2023** | **482,339** |
| Share pool increase | 2,153,117 |
| Forfeited | 169,690 |
| RSU grants | (275,000) |
| Option grants | (2,411,100) |
| **Available as of December 31, 2024** | **119,046** |

***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, 2024, the shares available for future grant under the Amended and Restated Plan are as follows:

| | Shares Available for Grant |
|---|---|
| **Available as of December 31, 2023** | **—** |
| Share pool increase | 600,000 |
| Forfeited | 40,000 |
| RSU grants | (15,000) |
| Option grants | (338,500) |
| **Available as of December 31, 2024** | **286,500** |

***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 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, 2024:

| | Number of Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (Years) | Aggregate Intrinsic Value* |
|---|---|---|---|---|
| **Outstanding, December 31, 2023** | **498,298** | **$ 8.96** | **7.24** | **$ 20,441** |
| Granted | 2,749,600 | 7.97 | | |
| Exercised | (1,605) | 3.50 | | |
| Forfeited | (16,848) | 78.91 | | |
| Cancelled | (192,842) | 8.22 | | |
| **Outstanding, December 31, 2024** | **3,036,603** | **$ 7.72** | **8.91** | **$ 22,624** |
| **Exercisable, December 31, 2024** | **707,396** | **$ 10.55** | **6.63** | **$ 7,069** |
| **Vested and expected to vest, December 31, 2024** | **3,036,603** | **$ 7.72** | **8.91** | **$ 22,624** |

**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, 2024 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, 2024 and 2023, was $6.04 and $2.95, respectively. The total fair value of the stock options that vested during the years ended December 31, 2024 and 2023 was $4,034,671 and $512,470, 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, | |
|---|---|---|
| | 2024 | 2023 |
| Dividend yield | 0.00 % | 0.00 % |
| Risk-free interest rate | 3.69-4.48% | 3.86-4.61% |
| Expected term (years) | 5.27-6.08 | 5.27-6.08 |
| Volatility | 81.73-99.96% | 87.93-127% |

*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 | 2023 |
| Dividend yield | 0.00% | 0.00% |
| Volatility factor | 93.71% | 87.4 - 87.9% |
| Risk-free interest rate | 4.16% | 4.21 - 4.54% |
| Derived service periods (years) | 1.27 - 2.48 | 0.81 - 3.11 |

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 |

On August 25, 2023, the Company granted RSUs to its executive management team and to certain members of the Board with market and performance based conditions. The RSUs are eligible to vest subject to the achievement and attainment of certain market capitalization target goals (market-based conditions) or the achievement of a successful exit (a performance-based condition); provided, however, that no RSUs shall vest until the Compensation Committee of the Board determines that shares can be sold into the market to cover withholding tax obligations associated with the vesting of the RSUs.

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

| | Year Ended December 31, 2023 |
|---|---|
| Dividend yield | 0.00% |
| Volatility factor | 87.4- 87.9% |
| Risk-free interest rate | 4.21- 4.54% |
| Derived service periods (years) | 0.81 - 3.11 |

The following is a summary of restricted stock unit activity during the year ended December 31, 2024:

| | Number of Shares | Weighted Average Grant Date Fair Value |
|---|---|---|
| **Unvested, December 31, 2023** | **847,777** | **$ 3.66** |
| Granted | 290,000 | 13.87 |
| Released | (634,664) | 3.58 |
| **Unvested, December 31, 2024** | **503,113** | **$ 9.62** |

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.

***Awards Granted Outside the 2014 Amended and Restated Plan***

During the year ended December 31, 2023, the Company granted shares of common stock to a non-employee consultant for investor relations services. Half of the shares were issued upon entering each service contract and the remaining half was issued on September 30, 2024.

The following is a summary of restricted stock activity outside of the 2014 Amended and Restated Plan during the year ended December 31, 2024:

| | Number of Shares | Weighted Average Grant Date Fair Value |
|---|---|---|
| **Unvested, December 31, 2023** | **5,000** | **$ 1.55** |
| Granted | — | — |
| Released | (5,000) | — |
| ***Unvested, December 31, 2024** | **—** | **$ —** |

***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 5), and the RSUs discussed above, in its Consolidated Statements of Operations as follows:

| | Year Ended December 31, | |
|---|---|---|
| | **2024** | **2023** |
| Research and development | $ 1,514,921 | $ 188,886 |
| General and administrative | 6,802,559 | 798,624 |
| | **$ 8,317,480** | **$ 987,510** |

The total amount of unrecognized compensation cost was $14,725,872 as of December 31, 2024. This amount will be recognized over a weighted-average period of 2.73 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, 2024, no shares were issued under the ESPP. The compensation expense, computed using the Black-Scholes model was immaterial.

**9. 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, 2024 | | |
|---|---|---|---|
| | **Loss (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)** |

| | For the Year Ended December 31, 2023 | | |
|---|---|---|---|
| | **Income (Numerator)** | **Shares (Denominator)** | **Per-Share Amount** |
| Net loss | $ (37,644,784) | | |
| **Basic EPS and diluted EPS** | | | |
| Net loss available to common stockholders | (37,644,784) | 7,006,038 | **$ (5.37)** |

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, | |
|---|---|---|
| | **2024** | **2023** |
| Stock options | 3,036,603 | 498,298 |
| Unvested restricted stock units | 503,113 | 847,777 |
| Unvested restricted stock (service provider) | — | 5,000 |
| Common shares underlying convertible debt | — | 968,973 |
| Warrants | 3,202,944 | 3,280,940 |
| **Total** | 6,742,660 | 5,600,988 |

**10. Income Taxes**

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

| | Year Ended December 31, | |
|---|---|---|
| | **2024** | **2023** |
| United States | $ (27,495,672) | $ (25,799,330) |
| Foreign | 938,620 | (11,841,854) |
| **Pre-tax loss and comprehensive loss from operations** | **$ (26,557,052)** | **$ (37,641,184)** |

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

| | Year Ended December 31, | |
|---|---|---|
| **Current income tax expense** | **2023** | **2022** |
| Federal | $ — | $ — |
| State | 10,071 | 3,600 |
| Foreign | — | — |
| **Total current income tax expense** | $ 10,071 | $ 3,600 |

The Company is subject to taxation in the United States, various states, Australia, and Canada. The Company's tax years for 2021 (federal), 2020 (States), 2020 (Australia) and 2020 (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, 2024, the Company had federal and state NOLs aggregating $123,364,920 and $140,454,552, respectively. If not used, $46,622,953 of Federal NOLs and $140,454,552 of state NOLs will begin to expire in 2031, $76,741,967 of federal NOLs and $— of state NOLs will carry forward indefinitely subject to an 80% limitation against taxable income. At December 31, 2024, the Company had Australia NOLs aggregating $312,009 which do not expire and $39,907,863 of Canadian NOLS which begin to expire in 2025.

At December 31, 2024, the Company had Canadian capital loss carryforwards of approximately $56,552,498 which may be carried forward indefinitely.

At December 31, 2024, the Company had federal and California research credit carryforwards of $4,764,557 and $2,187,816, 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, 2024 of $865,827 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 are as follows:

| | As of December 31, | |
|---|---|---|
| **Current deferred tax assets and (liabilities):** | **2024** | **2023** |
| Net operating loss | $ 41,627,022 | $ 40,900,348 |
| Capital loss carryforwards | 14,986,412 | 17,157,029 |
| Contingent legal accrual | 381,938 | 1,320,526 |
| Depreciation | 477,024 | 663,197 |
| Amortization | 2,606 | 225,678 |
| Research and development credits | 4,112,293 | 3,694,501 |
| Capitalized research and development costs | 4,708,931 | 1,835,326 |
| Lease liability | 95,674 | 51,086 |
| State taxes | 1,092 | 777 |
| Stock-based compensation | 1,174,967 | 312,735 |
| Other | 270,088 | 350,331 |
| **Gross deferred tax assets** | **67,838,047** | **66,511,533** |
| Valuation allowance | (67,743,575) | (66,461,557) |
| **Net deferred tax assets** | **$ 94,472** | **$ 49,976** |
| **Deferred tax liabilities** | | |
| Right-of-use asset | $ (94,472) | $ (49,976) |
| **Total deferred tax liabilities** | **(94,472)** | **(49,976)** |
| **Net deferred tax assets** | **$ —** | **$ —** |

The provision for income taxes on earnings subject to income taxes differs from the statutory Federal rate at December 31, 2024 and 2023, due to the following:

| | As of December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Expected income tax benefit at federal statutory tax rate | $ (5,576,981) | $ (7,904,649) |
| State income taxes, net of federal benefit | (1,871,588) | (847,810) |
| Change in valuation allowance | 2,522,618 | 3,167,507 |
| Uncertain tax positions | 2,562,991 | 1,008,482 |
| Reduction in deferreds upon divestiture | 839,873 | — |
| Stock compensation | (46,422) | 100,958 |
| Research and development credits | (1,374,591) | (315,498) |
| Rate adjustment | 6,070 | 6,042 |
| Foreign rate differential | 2,396,433 | (1,918,633) |
| Divestiture of VDL | — | 2,269,297 |
| In process research and development | — | 4,455,195 |
| 162(m) officers compensation | 460,853 | 27,942 |
| Other | 90,815 | (45,234) |
| **Provision for income taxes** | **$ 10,071** | **$ 3,600** |

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 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, 2024. During the year ended December 31, 2024, the valuation allowance increased by $1,282,018.

The Tax Cuts and Jobs Act of 2017 subjects a U.S. shareholder to tax on global intangible low-taxed income ("GILTI") earned by certain foreign subsidiaries. The FASB Staff Q&A, Topic 740, No. 5, *Accounting for Global Intangible Low-Taxed Income*, states that an entity can make an accounting policy election to recognize deferred taxes for temporary basis differences expected to reverse as GILTI in future years or to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only. The Company elects to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only.

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, | |
|---|---|---|
| | 2024 | 2023 |
| **Unrecognized tax positions, beginning of the year** | **$ 6,432,143** | **$ 2,872,020** |
| Gross increase - current period tax positions | 3,073,575 | 1,243,191 |
| Gross increase - prior period tax positions | — | 2,316,932 |
| Gross decrease – prior period tax positions | (7,277) | — |
| **Unrecognized tax positions, end of year** | **$ 9,498,441** | **$ 6,432,143** |

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 does not expect any significant increases or decreases to the Company's unrecognized tax positions within the next twelve months.

The Company had no accrual for interest or penalties on the Company's Consolidated Balance Sheets at December 31, 2024 and 2023 and has not recognized interest and/or penalties in the Consolidated Statements of Operations for the years then ended.

## 11. 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, 2024 and 2023, lease expense comprised of $130,658 and $97,986, 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, 2024 |
|---|---|
| Weighted-average remaining term – operating lease (in years) | 2.62 |
| Weighted-average discount rate – operating lease | 11.41 % |

Future minimum lease payments as of December 31, 2024 are presented in the following table:

| | |
|---|---|
| Year: | |
| 2025 | 215,127 |
| 2026 | 202,876 |
| 2027 | 85,936 |
| Total future minimum lease payments: | 503,939 |
| Less imputed interest | 48,349 |
| Total | **$ 455,590** |

Reported as:

| | December 31, 2024 | December 31, 2023 |
|---|---|---|
| Operating lease liability | $ 182,428 | $ 72,038 |
| Operating lease liability, net of current portion | 273,162 | 171,230 |
| Total lease liability | **$ 455,590** | **$ 243,268** |

***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 set a scheduling conference for March 31, 2025.

During the year ended December 31, 2024, management revised its assumptions related to its estimate of the legal contingency and the 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.

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.

*Skye Bioscience, Inc. vs Partner Re Ireland Insurance*

In February 2023, the Company brought a suit against the Company's D&O insurance carrier, Partner Re Ireland Insurance DAC ("Partner Re"), bringing claims for (a) breach of contract, (2) tortious breach of the implied covenant of good faith and fair dealing and (3) declaratory relief that Partner Re is obligated to reimburse the Company for the defense fees and costs incurred in defense of the Cunning Lawsuit and must indemnify the Company for any settlement or judgment in the Cunning Lawsuit (the "Partner Re Lawsuit"). The Company's allegations arise out of Partner Re's refusal to reimburse the Company for costs incurred by the Company in defending the Cunning Lawsuit. The case, entitled *Skye Bioscience, Inc., v. Partner Re Ireland Insurance DAC*, was filed in the United Stated District Court for the Central District of California.

On December 3, 2024, the Company entered into a settlement agreement with Partner Re for $2,000,000 in exchange for a full and final release of any future claims. For the year ended December 31, 2024 the Company recognized the income from insurance recovery in its consolidated statements of operations.

## 12. 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, | |
|---|---|---|
| | **2024** | **2023** |
| External clinical development expenses [1] | | |
| SBI-100 | $2,033,722 | $3,427,631 |
| nimacimab | 10,883,885 | 113,575 |
| Cost to acquire IPR&D asset | — | 21,215,214 |
| Personnel related and stock-based compensation | 3,995,558 | 1,811,138 |
| Other research and development expenses [2] | 1,788,529 | 467,117 |
| Total research and development expenses | **$18,701,694** | **$27,034,675** |

(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 $144,006, and $134,554 for December 31, 2024 and December 31, 2023, respectively. The amount of property and equipment outside of the US was equal to $1,522,258, and $4,156 for December 31, 2024 and December 31, 2023, respectively.

## 13 Subsequent Events

### *Stock Option Grants*

Subsequent to December 31, 2024, the Company granted an aggregate of 1,160,000 and 56,000 common stock options to members of management, employees and directors under the Amended and Restated Plan and Inducement Plan, respectively.

**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 | Pre 2015 Common Stock Warrants (incorporated by reference to Exhibit 4.2 to our Current Report on Form 8-K filed on November 3, 2014) |
| 4.2 | 2015, 2016 and 2017 Form of Common Stock Warrant (incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed August 20, 2015) |
| 4.4 | 2019 Common Stock Warrants (incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed on November 21, 2019) |
| 4.5 | 2020 Common Stock Warrants (incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed on August 5, 2020) |
| 4.6 | 2021 Inducement Warrants (incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q filed November 10, 2021) |
| 4.7 | 2021 Common Stock Warrants (incorporated by reference to Exhibit 4.1 to our Quarterly Report on Form 10-Q filed November 10, 2021) |
| 4.8 | 2021 Pre-Funded Warrants (incorporated by reference to Exhibit 4.2 to our Quarterly Report on Form 10-Q filed November 10, 2021) |
| 4.9 | 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) |
| 4.10 | 2022 Form of Warrant Issued to Former EHT Warrant Holders (incorporated by reference to Exhibit 4.12 to our Annual Report on Form 10-K filed on March 31, 2023) |
| 4.11 | 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) |
| 4.12 | 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) |

| | |
|---|---|
| 4.13 | 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) |
| 4.14 | 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) |
| 4.15# | Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 |
| 10.1†# | Skye Bioscience, Inc. Amended and Restated Omnibus Incentive Plan and form of stock option agreements and form of restricted stock agreements thereunder |
| 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 |
| 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) |
| 10.7† | Employment Agreement, dated October 4, 2021, by and between Skye Bioscience, Inc. and Kaitlyn Arsenault (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on October 6, 2021) |
| 10.8† | Amendment to Executive Employment Agreement, dated May 11, 2023, by and between Skye Bioscience, Inc. and Kaitlyn Arsenault (incorporated by reference to Exhibit 10.5 to our Quarterly Report on Form 10-Q filed on May 12, 2023) |
| 10.9† | Employment Agreement, dated August 30, 2024, by and between Skye Bioscience, Inc. and Puneet Arora (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on September 4, 2024) |
| 10.10†# | Employment Agreement, dated October 5, 2020, by and between Skye Bioscience, Inc. and Tu Diep |
| 10.11†# | Employment Agreement, dated November 11, 2022 by and between Skye Bioscience, Inc. and Chris Twitty |
| 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) |

| | |
|---|---|
| 19# | Skye Bioscience, Inc. Insider Trading Policy |
| 21.1# | Subsidiaries of the Registrant |
| 23.1# | 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 20, 2025 | By: | */s/ Punit Dhillon* |
| | | Punit Dhillon |
| | Its: | Director, Chief Executive Officer |
| | | (Principal Executive Officer) |
| March 20, 2025 | By: | */s/ Kaitlyn Arsenault* |
| | | Kaitlyn Arsenault |
| | Its: | Chief Financial 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 20, 2025 |
| | Punit Dhillon | |
| Its: | Director, Chief Executive Officer<br>(Principal Executive Officer) | |
| By: | */s/ Kaitlyn Arsenault* | March 20, 2025 |
| | Kaitlyn Arsenault | |
| Its: | Chief Financial Officer<br>(Principal Financial and Accounting Officer) | |
| By: | */s/ Paul Grayson* | March 20, 2025 |
| | Paul Grayson | |
| Its: | Director, Chairman | |
| By: | */s/ Deborah Charych* | March 20, 2025 |
| | Deborah Charych | |
| Its: | Director | |
| By: | */s/ Andrew J. Schwab* | March 20, 2025 |
| | Andrew J. Schwab | |
| Its: | Director | |
| By: | */s/ Karen Smith* | March 20, 2025 |
| | Karen Smith | |
| Its: | Director | |
| By: | */s/ Annalisa Jenkins* | March 20, 2025 |
| | Annalisa Jenkins | |
| Its: | Director | |